

SOLICITATION

SECTION A - SOLICITATION/CONTRACT FORM

1. Purchase Authority: Public Law 92-218 as amended		
2. Request for Proposal (RFP) Number: N02-CM-91000-16	3. Issue Date: July 24, 2008	4. Set Aside: [X] No [] Yes Part IV Section L
5. Title : Cancer Therapy Evaluation Program's Informatics and Computer Support		
6. ISSUED BY: Office of Acquisitions National Cancer Institute National Institutes of Health _____ _____ _____ _____	7. SUBMIT OFFERS TO: See Part III, Section J, "Packaging and Delivery of the Proposal," ATTACHMENT 1 of this Solicitation.	
8. Proposals for furnishing the supplies and/or services in THE SCHEDULE will be received at the place specified in, and in the number of copies specified in Attachment 1, "Packaging and Delivery of the Proposal," until 11:00 A.M. local time on August 25, 2008. Offers will be valid for 120 days unless a different period is specified by the offeror on the Attachment entitled, "Proposal Summary and Data Record, NIH 2043.		
9. THIS SOLICITATION REQUIRES DELIVERY OF PROPOSALS TO THE OFFICIAL POINT OF RECEIPT FOR THE PURPOSE OF DETERMINING TIMELY DELIVERY AS STATED IN ATTACHMENT 1, "PACKAGING AND DELIVERY OF THE PROPOSAL." IF YOUR PROPOSAL IS NOT RECEIVED BY THE CONTRACTING OFFICER OR HIS DESIGNEE AT THE PLACE AND TIME SPECIFIED, THEN IT WILL BE CONSIDERED LATE AND HANDLED IN ACCORDANCE WITH SUBPARAGRAPH (c)(3) OF FAR CLAUSE 52.215-1, ENTITLED, "INSTRUCTIONS TO OFFERORS--COMPETITIVE ACQUISITION" LOCATED IN SECTION L.1. OF THIS SOLICITATION.		
10. Offeror must be registered in the Central Contractor Registry (CCR) prior to award of a contract. http://www.ccr.gov		
11. FOR INFORMATION CALL: Annmarie L. Keane PHONE: 301-435-3814 e-MAIL: keanea@mail.nih.gov COLLECT CALLS WILL NOT BE ACCEPTED.		
		Annmarie L. Keane Contracting Officer Office of Acquisitions National Cancer Institute

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PART I - THE SCHEDULE

THE INFORMATION SET FORTH IN **SECTION A - SOLICITATION/CONTRACT FORM**, HEREIN CONTAINS IMPORTANT INFORMATION FOR ANY OFFEROR INTERESTED IN RESPONDING TO THIS SOLICITATION. ANY CONTRACT RESULTING FROM THIS SOLICITATION WILL INCLUDE IN ITS **SECTION A - SOLICITATION/ CONTRACT FORM**, ACCOUNTING, APPROPRIATION AND GENERAL INFORMATION APPLICABLE TO THE CONTRACT AWARD.

THE CONTRACT SCHEDULE SET FORTH IN **SECTIONS B THROUGH H**, HEREIN, CONTAINS CONTRACTUAL INFORMATION PERTINENT TO THIS SOLICITATION. IT IS NOT AN EXACT REPRESENTATION OF THE CONTRACT DOCUMENT THAT WILL BE AWARDED AS A RESULT OF THIS SOLICITATION. THE CONTRACT COST OR PRICE AND OTHER CONTRACTUAL PROVISIONS PERTINENT TO THE OFFEROR (i.e., those relating to the organizational structure [e.g., Non-Profit, Commercial] and specific cost authorizations unique to the Offeror's proposal and requiring Contracting Officer Prior Approval) WILL BE DISCUSSED IN THE NEGOTIATION PROCESS AND WILL BE INCLUDED IN THE RESULTANT CONTRACT. THE ENCLOSED CONTRACT SCHEDULE IS INTENDED TO PROVIDE THE OFFEROR WITH THE NECESSARY INFORMATION TO UNDERSTAND THE TERMS AND CONDITIONS OF THE RESULTANT CONTRACT.

SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS

ARTICLE B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES

To maintain, develop and expand the existing CTEP-ESYS (Cancer Therapy Evaluation Program -Enterprise System) to support the National Cancer Institute (NCI) research community and to migrate toward future NCI wide enterprise development initiatives.

ARTICLE B.2. ESTIMATED COST PLUS AWARD FEE AND AWARD TERM

a. Estimated Cost and Base Fee

1. The total estimated cost of the Base Period of this contract is \$_____.
2. If the Government exercises its option pursuant to the OPTION PROVISION Article in SECTION H of this contract, the estimated cost shall be increased as follows:

	Estimated Cost (\$)
Base Period:	
Option:	
Total [Base Period and Option]	

3. The total base fee (i.e. minimum fee payable hereunder) for the Base Period of the contract is \$_____.
- a. The Contractor is authorized to bill for partial fee payments of the Available Award Fee. Such partial payments shall consist of ___% of the total Available Award Fee for the Evaluation Period effective during the billing period.
 - b. Payment shall be subject to the withholding provision of the clauses ALLOWABLE COST AND PAYMENT and AWARD FEE referenced in the General Clause Listing in Part II, ARTICLE I.1. of this contract. Payment of fee shall not be made in less than monthly installments.

b. Award Fee Consideration

1. Based on the evaluation/determination described in subparagraph d. below, an award fee may be paid to the Contractor at regular intervals as defined in the paragraphs herein. The total potential award fee available is \$_____ and the evaluation periods shall be as follows:

Base Period Evaluation Period(s):	Available Award Fee

2. If the Government exercises its option pursuant to the OPTION PROVISION Article in SECTION H of this contract, the total potential award fee available for the option years/periods and the evaluation periods shall be as follows:

OPTION	Evaluation Period(s) by Option	Available Award Fee

c. Award Term

If the Award Terms are earned pursuant to the AWARD TERM QUALITY ASSURANCE SURVEILLANCE PLAN (QASP) Article in SECTION H of this contract, the Government's total estimated contract amount represented by the sum of the estimated cost plus the award fee will be increased as follows:

	Estimated Cost (\$)	Award Fee (\$)	Estimated Costs Plus Award Fee(s):
Base Period			
Award Terms			
Total Base Period and Award Term			

d. Total Estimated Contract Amount

1. The total estimated amount of the contract, represented by the sum of the estimated cost plus the available award fee is \$_____.
2. If the Government exercises its option pursuant to the OPTION PROVISION Article in SECTION H of this contract, and if the Award terms are earned pursuant to the AWARD TERM QUALITY SURVEILLANCE PLAN (QASP-AWARD TERM) Article in Section H of this contract, the Government's total estimated contract amount, represented by the sum of the estimated cost plus the available award fee will be increased as follows:

	Estimated Cost (\$)	Available Award Fee (\$)	Estimated Cost Plus Award Fee (\$)
Base Period:			
Option:			
Award Terms			

	Estimated Cost (\$)	Available Award Fee (\$)	Estimated Cost Plus Award Fee (\$)
Total [Base Period and Option]			

3. Total funds currently available for payment and allotted to this contract are \$_____ of which \$_____ represents the estimated costs, and of which \$_____ Represents the available award fee. For further provisions on funding, see the LIMITATION OF FUNDS clause referenced in Part II, ARTICLE I.2. Authorized Substitutions of Clauses.
4. It is estimated that the amount currently allotted will cover performance of the contract through _____.
5. The Contracting Officer may allot additional funds to the contract without the concurrence of the Contractor.

e. Methodology for Award Fee Evaluation/Determination

1. The Contractor's performance hereunder will be observed and evaluated continuously by the Government. At the end of each evaluation period, the Contracting Officer will review performance based on the standards and criteria established in the Quality Assurance Surveillance Plan-Award Fee, dated _____, listed in SECTION J - ATTACHMENT #5, attached hereto and made a part of this contract.
2. The findings of the evaluation will determine the amount of the available award fee (specified in subparagraph b. above) earned by the Contractor for the identified evaluation period. In no event, however, will any unearned award fee become available in subsequent evaluation periods.
3. The Contracting Officer will notify the Contractor, in writing, of the available award fee actually earned for a given evaluation period. Upon receipt of this notification, the Contractor may submit a public voucher for payment of the total award fee earned, less any previously billed partial payments authorized in subparagraph a. 3. (a) of this Article.
4. The evaluation/determination of award fee shall be binding on both parties and not subject to the Disputes clause included in Section I of the contract.

ARTICLE B.3. PROVISIONS APPLICABLE TO DIRECT COSTS

This article will prohibit or restrict the use of contract funds, unless otherwise approved by the Contracting Officer. The following is a list of items that may be included in the resultant contract as applicable. 1) Acquisition, by purchase or lease, of any interest in real property; 2) Special rearrangement or alteration of facilities; 3) Purchase or lease of any item of general purpose office furniture or office equipment regardless of dollar value; 4) Travel Costs; 5) Consultant Costs; 6) Subcontract Costs; 7) Patient Care Costs; 8) Accountable Government Property; and 9) Research Funding.

ARTICLE B.4. ADVANCE UNDERSTANDINGS

Specific elements of cost, which normally require prior written approval of the Contracting Officer before incurrence of the cost (e.g., foreign travel, consultant fees, subcontracts) will be included in this Article if the Contracting Officer has granted his/her approval prior to contract award.

SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

ARTICLE C.1. STATEMENT OF WORK

- a. Independently and not as an agent of the Government, the Contractor shall be required to furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government, as needed to perform the Statement of Work, dated July 2008, attached hereto and made a part of this Solicitation (See SECTION J - List of Attachments).

ARTICLE C.2. REPORTING REQUIREMENTS

All reports required herein shall be submitted in electronic format. In addition, one (1) hardcopy of each report shall be submitted to the Contracting Officer, unless otherwise specified.

a. **Technical Progress Reports**

1. In addition to the required reports set forth elsewhere in this Schedule, the preparation and submission of regularly recurring Technical Progress Reports will be required in any contract resulting from this solicitation. These reports will require descriptive information about the activities undertaken during the reporting period and will require information about planned activities for future reporting periods. The frequency and specific content of these reports will be determined prior to contract award. *[Note: Beginning May 25, 2008, the Contractor shall include the applicable PubMed Central or NIH Manuscript Submission reference number when citing publications that arise from its NIH funded research.]*

For proposal preparation purposes only, it is estimated that in addition to the required electronic version(s) 1 hard copies of these reports will be required as follows:

- Monthly
- Quarterly
- Semi-Annually
- Annually
- Annually (with a requirement for a Draft Annual Report)
- Final - Upon final completion of the contract
- Final - Upon final completion of the contract (with a requirement for a Draft Final Report)

b. **Reports/Deliverables**

1. Earned Value Management (EVM) reports - EVM data is entered into the ProSight system on a monthly basis. EVM reports will be reviewed by the Project Officer (PO) in consultation with the Contract Officer (CO) to validate cost and schedule variances to determine acceptable levels before the EVM information is entered into ProSight system for OMB submission. The report shall be delivered to the PO 20 calendar days prior to the designated monthly submission date into the ProSight system. If levels are outside acceptable levels, the contractor shall draft an explanation to be reviewed by the PO on causation and mitigation efforts to re-establish acceptable variance levels. All drafted explanations will be dated, signed off by the PO, and attached to EVM reports.

2. Monthly Progress Reports: The Contractor shall prepare and submit a monthly progress report that describes by sub-project, the monthly and cumulative hours and dollars spent. Development and maintenance and operations costs should be itemized separately. The plan shall be in a format that is exportable to Excel. Projected estimates for each column shall be provided for comparison. Monthly and cumulative grand totals

for the entire project shall also be provided. Hourly and dollar variance for the entire project shall be provided. Projected project and sub-project end dates should be provided based on dollars and hours.

3. Data Quality Reports -As the CTEP-ESYS matures, data quality will be critical to maintaining information assurance and data integrity. At the discretion of the PO, the contractor shall prepare and submit data quality reports on data discrepancies encountered with applications that are central to the mission of CTEP (i.e., adverse events, patient accruals, number of active organizations). The Contractor shall track data quality report discrepancies and followed up for resolution and document the details. The Contractor shall compile and incorporate data quality information into an enterprise scorecard for Total Quality Management efforts as deemed necessary to maintain effective data governance.

4. Quarterly Financial reports supporting Capital Planning and Investment Control (CPIC) -The Contractor shall prepare and submit quarterly financial reports to support OMB submission requirements for a major CPIC investment. The report shall be utilized as a managerial tool to keep the project on target to meet performance milestones as defined by ANSI/EIA Standard 748. The reports shall provide continuous guidance on planning, scheduling, and budgeting to define the work, assign responsibilities, define indirect procedures, establish proper management controls, schedule the work, authorized all work, time phase the work, and develop cost accounts.

5. Final Report: The Contractor shall prepare and submit a final report that includes a summation of the work performed and results obtained for the entire contract period of performance. This report shall be in sufficient detail to describe comprehensively the work conducted. A final report shall be submitted on or before the last day of the contract performance period.

6. Source Code and Object Code Unless otherwise specified herein, the Contractor shall deliver to the Government, upon the expiration date of the contract, all source code and object code developed, modified, and/or enhanced under this contract.

SECTION D - PACKAGING, MARKING AND SHIPPING

All deliverables required under this contract shall be packaged, marked and shipped in accordance with Government specifications. At a minimum, all deliverables shall be marked with the contract number and Contractor name. The Contractor shall guarantee that all required materials shall be delivered in immediate usable and acceptable condition.

SECTION E - INSPECTION AND ACCEPTANCE

- a. The Contracting Officer or the duly authorized representative will perform inspection and acceptance of materials and services to be provided.
- b. For the purpose of this SECTION, _____ is the authorized representative of the Contracting Officer.
- c. Inspection and acceptance will be performed at:
National Cancer Institute
Rockville, MD

Acceptance may be presumed unless otherwise indicated in writing by the Contracting Officer or the duly authorized representative within 30 days of receipt.

- d. This contract incorporates the following clause by reference, with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available.

FAR Clause 52.246-5, Inspection of Services - Cost-Reimbursement (April 1984).

SECTION F - DELIVERIES OR PERFORMANCE

ARTICLE F.1. DELIVERIES

Satisfactory performance of the final contract shall be deemed to occur upon performance of the work described in the Statement of Work Article in SECTION C of this contract and upon delivery and acceptance by the Contracting Officer, or the duly authorized representative, of the following items in accordance with the stated delivery schedule:

- a. The items specified below as described in the REPORTING REQUIREMENTS Article in SECTION C of this contract. will be required to be delivered F.o.b. Destination as set forth in FAR 52.247-35, F.o.b. DESTINATION, WITHIN CONSIGNEES PREMISES (APRIL 1984), and in accordance with and by the date(s) specified below:

1. Statement of Work Deliverables

Item	Description	SOW Reference	Delivered To	Due Date
1.	Master Project Plan	5.12.2	Project Officer	May 1
2.	Application Specific Project Plan	5.12.3	Project Officer	As requested by the Project Officer
3.	Application Specific Project Plan	5.12.4	Project Officer	As requested by the Project Officer
4.	Change Management Plan	5.12.7	Project Officer	As requested by the Project Officer

2. Reporting Requirement Deliverables

Item	Deliverable Description	(Quantity) and Delivered To	Due Date
1.	Earned Value Management (EVM) Reports	Project Officer	20 calendar days prior to the designated monthly submission date into the ProSight system
2.	Monthly Progress Reports	Project Officer (1) Contracting Officer	15th of the month following reporting period
3.	Data Quality Reports	Project Officer	As requested by the Project Officer
4.	Quarterly Financial reports	Project Officer	Submit with EVM report for the reporting quarter
5.	Final Report	Project Officer (1) Contracting Officer	Contract Expiration

ARTICLE F.2. CLAUSES INCORPORATED BY REFERENCE, FAR 52.252-2 (FEBRUARY 1998)

This contract incorporates the following clause(s) by reference, with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available. Also, the full text of a clause may be accessed electronically at this address: <http://www.acquisition.gov/comp/far/index.html>

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1) CLAUSE:

52.242-15, Stop Work Order (August 1989) with **Alternate I** (April 1984).

SECTION G - CONTRACT ADMINISTRATION DATA

ARTICLE G.1. PROJECT OFFICER

The following Project Officer(s) will represent the Government for the purpose of this contract:

To be specified prior to award

The Project Officer is responsible for: (1) monitoring the Contractor's technical progress, including the surveillance and assessment of performance and recommending to the Contracting Officer changes in requirements; (2) interpreting the statement of work and any other technical performance requirements; (3) performing technical evaluation as required; (4) performing technical inspections and acceptances required by this contract; and (5) assisting in the resolution of technical problems encountered during performance.

The Contracting Officer is the only person with authority to act as agent of the Government under this contract. Only the Contracting Officer has authority to: (1) direct or negotiate any changes in the statement of work; (2) modify or extend the period of performance; (3) change the delivery schedule; (4) authorize reimbursement to the Contractor for any costs incurred during the performance of this contract; or (5) otherwise change any terms and conditions of this contract.

The Contracting Officer hereby delegates the Project Officer as the Contracting Officer's authorized representative responsible for signing software license agreements issued as a result of this contract.

The Government may unilaterally change its Project Officer designation.

ARTICLE G.2. KEY PERSONNEL, HHSAR 352.270-5 (January 2006)

The key personnel specified in this contract are considered to be essential to work performance. At least 30 days prior to diverting any of the specified individuals to other programs or contracts (or as soon as possible, if an individual must be replaced, for example, as a result of leaving the employ of the Contractor), the Contractor shall notify the Contracting Officer and shall submit comprehensive justification for the diversion or replacement request (including proposed substitutions for key personnel) to permit evaluation by the Government of the impact on performance under this contract. The Contractor shall not divert or otherwise replace any key personnel without the written consent of the Contracting Officer. The Government may modify the contract to add or delete key personnel at the request of the Contractor or Government.

(End of Clause)

The following individual(s) is/are considered to be essential to the work being performed hereunder:

Name	Title

ARTICLE G.3. RECIPIENTS REIMBURSEMENT PROCEDURES

a. The Contractor shall provide scheduled reports and special CTEP-ESYS queries to third party sources (i.e., Collaborators with whom CTEP is co-developing investigational agents; Companies supplying agents for CTEP-sponsored or CTEP-approved trials; Cooperative Groups; investigators; etc.). To protect patient confidentiality and proprietary data, all requests from non-CTEP sources shall first be reviewed and approved by the CTEP Regulatory Affairs Branch (RAB). The Project Officer shall be carbon copied on all correspondence to RAB. A copy of all information sent to the third party source shall also be sent to the Regulatory Affairs Branch at the time it is sent to the company.

b. The Contractor shall bill the third party directly for the services provided in support of CTEP-ESYS scheduled reports and specialized queries. The Contractor shall utilize Government rates to determine

costs. To streamline the process, standard rates shall be developed for development and delivery or reports to third party sources. The standardized rates will be negotiated with the Government. The Contractor shall bill the services in accordance with the standardized rates. In the event that a query will exceed the standard rates, the Contractor shall notify the Project Officer and Contracting Officer, and a specialized rate will be negotiated with the third party source. Under no circumstances will the Contractor bill prices other than the standard rate without Project Officer and Contracting Officer approval. The following categories shall be utilized to determine the standardized rates.

Standard reports - previously identified and developed reports. This task should require minimal effort (<2hrs.).

Simple specialized queries - Ad hoc query that requires from 2 to 16 hours of effort.

Complex specialized queries - Ad hoc query that requires > 16 hours of effort.

Repeated distribution of one of the above reports.

c. The Contractor shall keep an accurate account of all payments received from CTEP-approved Collaborators and/or companies separate from other fiscal aspects of the contract. The Contractor shall record as credits on monthly invoices to the Government, all payments received from the third party sources. The income from third party sources must be credited to the Government in the billing period actually received. Thus, the Contractor shall bill the Government directly for payment of contract costs and shall subtract as a credit, all payments received from third party sources. The actual collections from billings to third party sources shall be offset against the gross billing, leaving a net amount due on the invoices.

The contractor shall account for the contract related income separately, in accordance with its own double-entry accounting system. The Contractor shall submit to the Government a Monthly Summary of Sales sheet, which is listed as Attachment 3 in Section J. LIST OF ATTACHMENTS of this contract. The Contractor shall submit a copy of this attachment each month with the Monthly Progress Report.

The administration of the contract related income shall be subject to the terms of this contract, including specifically and without limitation, FAR Clause 52.215-2, AUDIT-NEGOTIATION of the General Clauses, and the applicable cost principles of the Federal Acquisition Regulation.

d. The Contractor shall use the following procedures for collection of delinquent accounts:

Step 1 - Accounts 30 days past due. A copy of the invoice shall be sent to the recipient with a notation that the account is overdue and request payment.

Step 2 - Accounts 60 days past due. The Contractor shall turn the account over to a collection agency and notify the Project Officer.

e. When the completion (final) invoice is submitted on this contract, a listing of all outstanding Collaborator/company invoices shall be provided along with details as to what disposition is expected on each.

ARTICLE G.4. INVOICE SUBMISSION/CONTRACT FINANCING REQUEST AND CONTRACT FINANCIAL REPORT

a. Invoice/Financing Request Instructions and Contract Financial Reporting for NIH Cost-Reimbursement Type Contracts NIH(RC)-4 are attached and made part of this contract. The Contractor shall follow the attached instructions and submission procedures specified below to meet the requirements of a "proper invoice" pursuant to FAR Subpart 32.9, Prompt Payment.

1. Payment requests shall be submitted as follows:

a. One original to the following designated billing office:

National Institutes of Health
Office of Financial Management
Commercial Accounts

2115 East Jefferson Street, Room 4B-432, MSC 8500
Bethesda, MD 20892-8500

- b. One copy to the following approving official:

Contracting Officer
Office of Acquisitions
National Cancer Institute, NIH
EPS, Room 6056
6120 EXECUTIVE BLVD MSC 7193
BETHESDA, MD 20892- 7193

2. In addition to the requirements specified in FAR Subpart 32.9 for a proper invoice, the Contractor shall include the following information on all payment requests:

- a. Name of the Office of Acquisitions. The Office of Acquisitions for this contract is National Cancer Institute .
- b. Central Point of Distribution. For the purpose of this contract, the Central Point of Distribution is NCI OA Branch E - ncibranchinvoices@mail.nih.gov .
- c. Vendor Identification Number. This is the 7 digit number that appears after the Contractor's name in Block 7 of Standard Form 26. *[Note: This only applies to new contracts awarded on/ after June 4, 2007, and any existing contract modified to include the number.]*
- d. DUNS number or DUNS+4 that identifies the Contractor's name and address exactly as stated on the face page of the contract.
- e. Identification of whether payment is to be made using a two-way or three-way match. This contract requires a Two-Way match.

- b. Inquiries regarding payment of invoices shall be directed to the designated billing office, (301) - 496-6452.

ARTICLE G.5. INDIRECT COST RATES

In accordance with Federal Acquisition Regulation (FAR) (48 CFR Chapter 1) Clause 52.216-7 (d)(2), Allowable Cost and Payment incorporated by reference in this contract in PART II, SECTION I, the cognizant Contracting Officer representative responsible for negotiating provisional and/or final indirect cost rates is identified as follows:

Director, Division of Financial Advisory Services
Office of Acquisition Management and Policy
National Institutes of Health
6100 Building, Room 6B05
6100 EXECUTIVE BLVD MSC-7540
BETHESDA MD 20892-7540

These rates are hereby incorporated without further action of the Contracting Officer.

ARTICLE G.6. GOVERNMENT PROPERTY

If this RFP will result in the acquisition or use of Government Property provided by the contracting agency or if the Contracting Officer authorizes in the preaward negotiation process, the acquisition of property (other than real property), this ARTICLE will include applicable provisions and incorporate the HHS Publication, entitled, "Contractor's Guide for Control of Government Property," which can be found at:

<http://knownet.hhs.gov/log/AgencyPolicy/HHSLogPolicy/contractorsguide.htm>.

ARTICLE G.7. POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE

a. Contractor Performance Evaluations

Interim and final evaluations of Contractor performance will be prepared on this contract in accordance with FAR 42.15. The final performance evaluation will be prepared at the time of completion of work. In addition to the final evaluation, interim evaluation(s) shall be submitted (To be determined prior to contract award.).

Interim and final evaluations will be provided to the Contractor as soon as practicable after completion of the evaluation. The Contractor will be permitted thirty days to review the document and to submit additional information or a rebutting statement. If agreement cannot be reached between the parties, the matter will be referred to an individual one level above the Contracting Officer, whose decision will be final.

Copies of the evaluations, Contractor responses, and review comments, if any, will be retained as part of the contract file, and may be used to support future award decisions.

b. Electronic Access to Contractor Performance Evaluations

Contractors that have Internet capability may access evaluations through a secure Web site for review and comment by completing the registration form that can be obtained at the following address:

<http://oamp.od.nih.gov/OD/CPS/cps.asp>

The registration process requires the Contractor to identify an individual that will serve as a primary contact and who will be authorized access to the evaluation for review and comment. In addition, the Contractor will be required to identify an alternate contact who will be responsible for notifying the cognizant contracting official in the event the primary contact is unavailable to process the evaluation within the required 30-day time frame.

SECTION H - SPECIAL CONTRACT REQUIREMENTS

ARTICLE H.1. HUMAN SUBJECTS

It is hereby understood and agreed that research involving human subjects shall not be conducted under this contract, and that no material developed, modified, or delivered by or to the Government under this contract, or any subsequent modification of such material, will be used by the Contractor or made available by the Contractor for use by anyone other than the Government, for experimental or therapeutic use involving humans without the prior written approval of the Contracting Officer.

ARTICLE H.2. NEEDLE EXCHANGE

Pursuant to the current HHS annual appropriations act, the Contractor shall not use contract funds to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug.

ARTICLE H.3. PRESS RELEASES

Pursuant to the current HHS annual appropriations act, the Contractor shall clearly state, when issuing statements, press releases, requests for proposals, bid solicitations and other documents describing projects or programs funded in whole or in part with Federal money: (1) the percentage of the total costs of the program or project which will be financed with Federal money; (2) the dollar amount of Federal funds for the project or program; and (3) the percentage and dollar amount of the total costs of the project or program that will be financed by nongovernmental sources.

ARTICLE H.4. RESTRICTION ON EMPLOYMENT OF UNAUTHORIZED ALIEN WORKERS

Pursuant to the current HHS annual appropriations act, the Contractor shall not use contract funds to employ workers described in section 274A(h)(3) of the Immigration and Nationality Act, which reads as follows:

"(3) Definition of unauthorized alien. - As used in this section, the term 'unauthorized alien' means, with respect to the employment of an alien at a particular time, that the alien is not at that time either (A) an alien lawfully admitted for permanent residence, or (B) authorized to be so employed by this Act or by the Attorney General."

ARTICLE H.5. OPTION PROVISION

Unless the Government exercises its option pursuant to the Option Clause set forth in ARTICLE I.3., the contract will consist only of the Base Period of the Statement of Work as defined in Sections C and F of the contract. Pursuant to FAR Clause 52.217-8, Option to Extend Services set forth in ARTICLE I.3. of this contract, the Government may, by unilateral contract modification, require the Contractor to perform additional options set forth in the Statement of Work and also defined in Sections C and F of the contract. If the Government exercises this option, notice must be given at least 60 days prior to the expiration date of this contract, and the estimated cost plus award fee of the contract will be increased as set forth in the ESTIMATED COST PLUS AWARD FEE AND AWARD TERM.

ARTICLE H.6. AWARD TERM QUALITY ASSURANCE SURVEILLANCE PLAN (QASP)

a. Award Term Contract

The Contractor may earn award term(s) as described below. If the Contracting Officer determines that the Contractor's performance merits the award term, the estimated cost plus award fee will be increased as set forth in the ESTIMATED COST, AWARD FEE AND AWARD TERM Article in SECTION B of this contract.

b. Award Term Provisions

This contract has a base performance period of 3 years November 1, 2008 - October 31, 2011. The Contractor will have the opportunity to earn 4 additional years of work November 1, 2011 - October 31, 2015 using the evaluation process described herein. These additional years of work are called Award Terms. The total duration of this contract, including all Award Terms, shall not exceed a period of 7 years November 1, 2008 - October 31, 2015.

1. Method for Earning Award Term(s)

- a. The Contractor's performance under this contract will be observed and evaluated continuously by the Government. The Contractor Assessment Report will be used to assess Contractor performance and determine whether the Contractor will receive Award Term(s). The Contractor Assessment Report includes Performance Indicators and Standards which identify the indicators to be evaluated and the associated standards for each indicator. A copy of the "Contractor Assessment Report/Performance Indicators and Standards," dated _____ is included as an attachment in SECTION J of this contract.
- b. The "Contractor Assessment Report/Performance Indicators and Standards" will be prepared by the Government, resulting in an overall rating which will be disseminated to the Contractor annually. The Award Term earned will be determined based upon review of the Contractor's performance against the performance indicators and standards as follows:
 1. Using the 0-5 point score in the Plan, the Contractor must receive an average of 3.5 or better for the first two years of Contractor performance. In years three, four and five, the Contractor must receive an average of 3.8 or better in each year to earn the Award Terms. These goals are intended to be a stretch for the Contractor, but achievable.
 2. At the conclusion of year two, in addition to the year two Contractor Assessment Report, the government will prepare a summary report which will set forth the average rating for the first two years' of performance and the year two rating. This summary report will be used to determine if the Award Term for year four has been earned. Likewise, at the conclusion of year three, the government will prepare a Contractor Assessment Report and a summary report of year three to determine if the Award Term for year five has been earned. At the conclusion of year four, the government will also prepare a Contractor Assessment Report and a summary report of year four to determine if the Award Term for year six has been earned. At the conclusion of year five, the government will also prepare a Contractor Assessment Report and a summary report of year five to determine if the Award Term for year seven has been earned.

The advance evaluation of performance is required to allow adequate time for recompetition of the requirement in the event that Contractor performance does not meet the Award Term requirements. If the Contractor does not earn the first Award Term, there will be no opportunity to earn subsequent Award Term(s) and the contract expiration date will remain unchanged.
- c. A unilateral contract modification to add the Award Term will be issued when scoring meets or exceeds that set forth in the contract. The Government shall issue this modification at least 60 days prior to contract expiration. The Award Term determination and the methodology for determining the award term are unilateral decisions made solely by the Government and are not subject to dispute.
- d. The "Contractor Assessment Report/Performance Indicators and Standards" described herein contains rating criteria used solely to assess whether the Contractor has earned the award term specified in this contract. This report differs from the Contractor Performance Report described in the POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE Article in SECTION G of this contract, which uses a standard rating criteria established for the Federal Contractor Performance System to evaluate overall contract performance. For this reason, the Contractor's performance scores for determining authorization of the award term(s) may differ from the Contractor's performance scores for overall contract performance.

2. Changes to the Contractor Assessment Report/Performance Indicators and Standards

Unilateral changes to the Contractor Assessment Report/Performance Indicators and Standards may be made if the Contractor is provided written notification by the Contracting Officer at least 30 days before the

start of the upcoming evaluation period. Changes affecting the current evaluation period must be by mutual agreement of both parties.

3. Contractor Performance Assessment

The Project Officer, and other Government personnel as appropriate, will use the "Contractor Assessment Report/Performance Indicators and Standards" and the associated performance elements and standards to score contract performance for the Award Term determination. The Contracting Officer is responsible for making the final decision on the Contractor's score and for determining whether the Contractor has earned the Award Term.

4. Contractor Performance Evaluation

The Project Officer and Contracting Officer will prepare reports required by FAR 42.15 and described in the POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE Article in SECTION G of this contract to determine the Contractor's overall contract performance. Unless specifically identified as a rating criterion in the "Contractor Assessment Report/Performance Indicators and Standards," this evaluation report will not be used in the Award Term determination.

ARTICLE H.7. SUBCONTRACTING PROVISIONS

a. **Small Business Subcontracting Plan**

1. The Small Business Subcontracting Plan, dated _____ is attached hereto and made a part of this contract.
2. The failure of any Contractor or subcontractor to comply in good faith with FAR Clause 52.219-8, entitled "Utilization of Small Business Concerns" incorporated in this contract and the attached Subcontracting Plan, will be a material breach of such contract or subcontract and subject to the remedies reserved to the Government under FAR Clause 52.219-16 entitled, "Liquidated Damages-Subcontracting Plan."

b. **Subcontracting Reports**

The Contractor shall submit the following Subcontracting reports electronically via the "electronic Subcontracting Reporting System (eSRS) at <http://www.esrs.gov>.

1. Individual Subcontract Reports (ISR)

Regardless of the effective date of this contract, the Report shall be due on the following dates for the entire life of this contract:

April 30th

October 30th

Expiration Date of Contract

2. Summary Subcontract Report (SSR)

Regardless of the effective date of this contract, the Summary Subcontract Report shall be submitted annually on the following date for the entire life of this contract:

October 30th

For both the Individual and Summary Subcontract Reports, the Contracting Officer shall be included as a contact for notification purposes at the following e-mail address:

keanea@mail.nih.gov

Contracting Officer

ARTICLE H.8. INFORMATION SECURITY

The Statement of Work (SOW) requires the Contractor to (1) develop, (2) have the ability to access, or (3) host and/or maintain a Federal information system(s). Pursuant to Federal and HHS Information Security Program Policies, the Contractor and any subcontractor performing under this contract shall comply with the following requirements:

Federal Information Security Management Act of 2002 (FISMA), Title III, E-Government Act of 2002, Pub. L. No. 107-347 (Dec. 17, 2002); <http://csrc.nist.gov/drivers/documents/FISMA-final.pdf>

a. Information Type

Administrative, Management and Support Information

Mission Based Information

b. Security Categories and Levels

Confidentiality Level: Low Moderate High

Integrity Level: Low Moderate High

Availability Level: Low Moderate High

Overall Level: **Low** **Moderate** **High**

c. Position Sensitivity Designations

1. The following position sensitivity designations and associated clearance and investigation requirements apply under this contract.

Level 6: Public Trust - High Risk (Requires Suitability Determination with a BI). Contractor employees assigned to a Level 6 position are subject to a Background Investigation (BI)

Level 5: Public Trust - Moderate Risk (Requires Suitability Determination with NACIC, MBI or LBI). Contractor employees assigned to a Level 5 position with no previous investigation and approval shall undergo a National Agency Check and Inquiry Investigation plus a Credit Check (NACIC), a Minimum Background Investigation (MBI), or a Limited Background Investigation (LBI).

Level 1: Non Sensitive (Requires Suitability Determination with an NACI). Contractor employees assigned to a Level 1 position are subject to a National Agency Check and Inquiry Investigation (NACI).

2. The Contractor shall submit a roster, by name, position, e-mail address, phone number and responsibility, of all staff (including subcontractor staff) working under the contract who will develop, have the ability to access, or host and/or maintain a Federal information system(s). The roster shall be submitted to the Project Officer, with a copy to the Contracting Officer, within 14 calendar days of the effective date of the contract. Any revisions to the roster as a result of staffing changes shall be submitted within 15 calendar days of the change. The Contracting Officer shall notify the Contractor of the appropriate level of suitability investigations to be performed. An electronic template, "Roster of Employees Requiring Suitability Investigations," is available for Contractor use at: <http://ais.nci.nih.gov/forms/Suitability-roster.xls>.

Upon receipt of the Government's notification of applicable Suitability Investigations required, the Contractor shall complete and submit the required forms within 30 days of the notification. Additional

submission instructions can be found at the "NCI Information Technology Security Policies, Background Investigation Process" website: <http://ais.nci.nih.gov>.

Contractor/subcontractor employees who have met investigative requirements within the past five years may only require an updated or upgraded investigation.

3. Contractor/Subcontractor employees shall comply with the HHS criteria for the assigned position sensitivity designations prior to performing any work under this contract. The following exceptions apply:

Levels 5 and 1: Contractor/Subcontractor employees may begin work under the contract after the Contractor has submitted the name, position and responsibility of the employee to the Project Officer, as described in paragraph c. (2) above.

Level 6: In special circumstances the Project Officer may request a waiver of the pre-appointment investigation. If the waiver is granted, the Project Officer will provide written authorization for the Contractor/Subcontractor employee to work under the contract.

d. Information Security Training

The Contractor shall ensure that each Contractor/Subcontractor employee has completed the NIH Computer Security Awareness Training course at: <http://irtsectraining.nih.gov/> prior to performing any contract work, and thereafter completing the NIH-specified fiscal year refresher course during the period of performance of the contract.

The Contractor shall maintain a listing by name and title of each Contractor/Subcontractor employee working under this contract that has completed the NIH required training. Any additional security training completed by Contractor/Subcontractor staff shall be included on this listing. [The listing of completed training shall be included in the first technical progress report. (See Article C.2. Reporting Requirements.) Any revisions to this listing as a result of staffing changes shall be submitted with next required technical progress report.]

Contractor/Subcontractor staff shall complete the following additional training prior to performing any work under this contract:

e. Rules of Behavior

The Contractor/Subcontractor employees shall comply with the NIH Information Technology General Rules of Behavior at: <http://irm.cit.nih.gov/security/nihitrob.html>.

f. Personnel Security Responsibilities

Contractor Notification of New and Departing Employees Requiring Background Investigations

1. The Contractor shall notify the Contracting Officer, the Project Officer, and the Security Investigation Reviewer **within five working days** before a new employee assumes a position that requires a suitability determination or when an employee with a security clearance stops working under the contract. The Government will initiate a background investigation on new employees requiring security clearances and will stop pending background investigations for employees that no longer work under the contract.
2. New employees: Provide the name, position title, e-mail address, and phone number of the new employee. Provide the name, position title and suitability level held by the former incumbent. If the employee is filling a new position, provide a description of the position and the Government will determine the appropriate security level.
3. Departing employees:
 - Provide the name, position title, and security clearance level held by or pending for the individual.

- Perform and document the actions identified in the "Employee Separation Checklist", attached in Section J, ATTACHMENTS of this contract, when a Contractor/Subcontractor employee terminates work under this contract. All documentation shall be made available to the Project Officer and/or Contracting Officer upon request.

g. Commitment to Protect Non-Public Departmental Information Systems and Data

1. Contractor Agreement

The Contractor and its subcontractors performing under this SOW shall not release, publish, or disclose non-public Departmental information to unauthorized personnel, and shall protect such information in accordance with provisions of the following laws and any other pertinent laws and regulations governing the confidentiality of such information:

- 18 U.S.C. 641 (Criminal Code: Public Money, Property or Records)
- 18 U.S.C. 1905 (Criminal Code: Disclosure of Confidential Information)
- Public Law 96-511 (Paperwork Reduction Act)

2. Contractor-Employee Non-Disclosure Agreements

Each Contractor/Subcontractor employee who may have access to non-public Department information under this contract shall complete the Commitment to Protect Non-Public Information - Contractor Agreement. A copy of each signed and witnessed Non-Disclosure agreement shall be submitted to the Project Officer prior to performing any work under the contract.

h. NIST SP 800-53 Self-Assessment

The contractor shall annually update and re-submit its Self-Assessment required by NIST SP 800-53, *Recommended Security Controls for Federal Information Systems*. (<http://csrc.nist.gov/publications> - under Special Publications).

Subcontracts: The Contractor's annual update to its Self-Assessment Questionnaire shall include similar information for any subcontractor that performs under the SOW to (1) develop a Federal information system(s) at the Contractor's/Subcontractor's facility, or (2) host and/or maintain a Federal information system(s) at the Contractor's/Subcontractor's facility.

The annual update shall be submitted to the Project Officer, with a copy to the Contracting Officer [For option contracts: no later than the completion date of the period of performance/ for all other contracts: indicate due date as determined by the Project Officer/Contracting Officer].

i. Information System Security Plan

The Contractor's draft ISSP submitted with its proposal shall be finalized in coordination with the Project Officer no later than 90 calendar days after contract award.

Following approval of its draft ISSP, the Contractor shall update and resubmit its ISSP to the Project Officer every three years or when a major modification has been made to its internal system. The Contractor shall use the current ISSP template in Appendix A of NIST SP 800-18, *Guide to Developing Security Plans for Federal Information Systems*. (<http://csrc.nist.gov/publications/nistpubs/800-18-Rev1/sp800-18-Rev1-final.pdf>). The details contained in the Contractor's ISSP shall be commensurate with the size and complexity of the requirements of the SOW based on the System Categorization determined above in subparagraph (b) Security Categories and Levels of this Article.

Subcontracts: The Contractor shall include similar information for any subcontractor performing under the SOW with the Contractor whenever the submission of an ISSP is required.

j. Common Security Configurations

The contractor shall ensure that any information technology acquired under this contract incorporates the applicable common security configuration established by the National Institute of Standards and Technology (NIST) at <http://checklists.nist.gov>.

ARTICLE H.9. ELECTRONIC AND INFORMATION TECHNOLOGY ACCESSIBILITY (January 2008)

Pursuant to Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1998, all electronic and information technology (EIT) products and services developed, acquired, maintained, and/or used under this contract/order must comply with the "Electronic and Information Technology Accessibility Provisions" set forth by the Architectural and Transportation Barriers Compliance Board (also referred to as the "Access Board") in 36 CFR part 1194. Information about Section 508 provisions is available at <http://www.section508.gov/>. The complete text of Section 508 Final provisions can be accessed at <http://www.access-board.gov/sec508/provisions.htm>.

The Section 508 standards applicable to this contract/order are identified in the Statement of Work. The contractor must provide a written Section 508 conformance certification due at the end of each order/contract exceeding \$100,000 when the order/contract duration is one year or less. If it is determined by the Government that EIT products and services provided by the Contractor do not conform to the described accessibility in the Product Assessment Template, remediation of the products and/or services to the level of conformance specified in the vendor's Product Assessment Template will be the responsibility of the Contractor at its own expense.

In the event of a modification(s) to the contract/order, which adds new EIT products and services or revised the type of, or specifications for, products and services the Contractor is to provide, including EIT deliverables such as electronic documents and reports, the Contracting Officer may require that the contractor submit a completed HHS Section 508 Product Assessment Template to assist the Government in determining that the EIT products and services support Section 508 accessibility requirements. Instructions for documenting accessibility via the HHS Section 508 Product Assessment Template may be found at <http://508.hhs.gov>.

[(End of HHSAR 352.270-19(b))]

Prior to the Contracting Officer exercising an option for a subsequent performance period/additional quantity or adding increment funding for a subsequent performance period under this contract, as applicable, the Contractor must provide a Section 508 Annual Report to the Contracting Officer and Contracting Officer's Technical Representative (also known as Project Officer or Contracting Officer's Representative). Unless otherwise directed by the Contracting Officer in writing, the Contractor shall provide the cited report in accordance with the following schedule. Instructions for completing the report are available at: <http://508.hhs.gov/> under the heading Vendor Information and Documents. The Contractor's failure to submit a timely and properly completed report may jeopardize the Contracting Officer's exercising an option or adding incremental funding, as applicable.

Schedule for Contractor Submission of Section 508 Annual Report:

To be determined prior to contract award.

[(End of HHSAR 352.270-19(c))]

ARTICLE H.10. ACCESS TO NATIONAL INSTITUTES OF HEALTH (NIH) ELECTRONIC MAIL

All Contractor staff that have access to and use of NIH electronic mail (e-mail) must identify themselves as contractors on all outgoing e-mail messages, including those that are sent in reply or are forwarded to another user. To best comply with this requirement, the Contractor staff shall set up an e-mail signature ("AutoSignature") or an electronic business card ("V-card") on each Contractor employee's computer system and/or Personal Digital Assistant (PDA) that will automatically display "Contractor" in the signature area of all e-mails sent.

ARTICLE H.11. EARNED VALUE MANAGEMENT SYSTEM

- a. This contract is a Tier 1 information technology investment and must apply Earned Value Management (EVM) principles for tracking investment cost, schedule, and performance in full compliance with American National Standards Institute-Electronic Industries Alliance (ANSI/EIA) Standard 748-A (Criteria 1-32).
- b. Earned Value Management (EVM) is a project management system used by the Contractor to effectively integrate the project technical scope of work with schedule and cost elements for optimum project planning and control. The qualities and operating characteristics of earned value management systems are described in American National Standards Institute (ANSI)/Electronic Industries Alliance (EIA) Standard-748- A-1998, Earned Value Management Systems, approved: May 19, 1998, Reaffirmed: August 28, 2002.
- c. In the performance of this contract the Contractor shall use an earned value management system (EVMS) to manage the contract that at the time of contract award has been recognized by the cognizant Contracting Officer as compliant with the guidelines in ANSI/EIA Standard-748 (current version at time of award) and the Contractor will submit reports in accordance with the requirements of this contract.
- d. If, at the time of award, the Contractor's EVMS has not been recognized by the Contracting Officer as complying with EVMS guidelines (or the Contractor does not have an existing cost/schedule control system that is compliant with the guidelines in ANSI/EIA Standard-748 (current version at time of award)), the Contractor shall apply the system to the contract and shall be prepared to demonstrate to the Contracting Officer that the EVMS complies with the EVMS guidelines referenced in paragraph (c) of this clause.
- e. If a pre-award Integrated Baseline Review (IBR) was not conducted, The Government will perform a post-award IBR as early as practicable after award. The Government may perform an IBR at exercise of significant options, or following incorporation of major modifications. The objective of the IBR is for the Government and the Contractor to jointly assess technical areas, such as the Contractor's planning, to ensure complete coverage of the statement of work, logical scheduling of the work activities, adequate resources, methodologies for claiming BCWP, and identification of inherent risks.
- f. Contractor-proposed EVMS changes require approval of the Contracting Officer prior to implementation. The Contracting Officer will advise the Contractor of the acceptability of such changes within 30 calendar days after receipt of the notice of proposed changes from the Contractor.
- g. The Contractor shall provide access to all pertinent records and data requested by the Contracting Officer. Access is to permit Government surveillance to ensure that the EVMS conforms, and continues to conform, to the performance criteria referenced in paragraph (a) of this clause.
- h. The Contractor shall require their subcontractors to comply with the performance criteria of this clause, and allow an authorized representative of the Contracting Officer to perform surveillance and monitor monthly EV performance. The Contractor shall conduct IBRs with Government participation for the Subcontractors specifically identified:
- i. The Contractor shall provide the project status information cited in the attached Contract Performance Report (CPR), Nos. 1 through 5 at an agreed upon level of the Work Breakdown Structure (WBS) on a monthly basis in XML or Microsoft Excel format. The first reporting period consists of the first full month of performance plus any fractional part of the initial month. Thereafter, the reporting period shall consist of each calendar month.
 1. Explain the reasons for all variances in cost, schedule, or performance.
 2. Estimate whether the performance goals will be achieved, and the impact to the cost and schedule goals. Discuss its official Estimate at Completion (EAC) and the differences, if any, between it and EAC's calculated by the Project Officer based on the Contractor's reported cost and schedule performance to date.
 3. Discuss the corrective actions that will be taken to mitigate all variances identified, the risk associated with the actions, how close these actions will bring the project to the original baseline and any proposed

baseline changes (if necessary). The Contractor must submit a corrective action plan to the Project Officer if cost, schedule, or performance variances equal or exceed plus or minus ten (10) percent.

ARTICLE H.12. CONFIDENTIALITY OF INFORMATION

The following information is covered by **HHSAR 352.224-70, Confidentiality of Information** (January 2006):

1. The contractor shall insure the confidentiality of the following data or information of the following data or information which may be made available to the Contractor in the course of the work to be performed hereunder: 1) confidential information about NCI investigators such as their registration status, address, phone numbers, FAX numbers and e-mail address; 2) proprietary information contained in Investigational New Drug Applications (INDs); proprietary data in any NCI databases; 4) confidential information about all clinical information collected, stored or analyzed through the CTEP databases; 5) all information regarding clinical trials and related proprietary data. Any dissemination of data relating to these documents and information shall be cleared through the Contracting Officer for the purpose of identifying any inadvertent disclosure of the data or information prior to any oral or written release of information. This includes any standard reports, ad hoc queries or abstracts.

ARTICLE H.13. REPORTING MATTERS INVOLVING FRAUD, WASTE AND ABUSE

Anyone who becomes aware of the existence or apparent existence of fraud, waste and abuse in NIH funded programs is encouraged to report such matters to the HHS Inspector General's Office in writing or on the Inspector General's Hotline. The toll free number is **1-800-HHS-TIPS (1-800-447-8477)**. All telephone calls will be handled confidentially. The e-mail address is Htips@os.dhhs.gov and the mailing address is:

Office of Inspector General
Department of Health and Human Services
TIPS HOTLINE
P.O. Box 23489
Washington, D.C. 20026

ARTICLE H.14. YEAR 2000 COMPLIANCE

In accordance with FAR 39.106, Information Technology acquired under this contract must be Year 2000 compliant as set forth in the following clause(s):

1. Service Involving the Use of Information Technology YEAR 2000 COMPLIANCE--SERVICE INVOLVING THE USE OF INFORMATION TECHNOLOGY

The Contractor agrees that each item of hardware, software, and firmware used under this contract shall be able to accurately process date data (including, but not limited to, calculating, comparing and sequencing) from, into and between the twentieth and twenty-first centuries and the Year 1999 and the Year 2000 and leap year calculations.

(End of Clause)

PART II - CONTRACT CLAUSES

SECTION I - CONTRACT CLAUSES

THE FOLLOWING ARTICLE I.1. GENERAL CLAUSE LISTING(S) WILL BE APPLICABLE TO MOST CONTRACTS RESULTING FROM THIS RFP. HOWEVER, THE ORGANIZATIONAL STRUCTURE OF THE SUCCESSFUL OFFEROR(S) WILL DETERMINE THE SPECIFIC GENERAL CLAUSE LISTING TO BE CONTAINED IN THE CONTRACT(S) AWARDED FROM THIS RFP:

The complete listing of these clauses may be accessed at:

<http://rcb.cancer.gov/rcb-internet/appl/general-clauses/clausesDGS.jsp>

General Clauses for a Cost-Reimbursement Service Contract

ARTICLE I.2. AUTHORIZED SUBSTITUTIONS OF CLAUSES

Any authorized substitutions and/or modifications other than the General Clauses which will be based on the type of contract/Contractor will be determined during negotiations.

It is expected that the following substitution(s) will be made part of the resultant contract:

- a. FAR Clause **52.232-20, Limitation Of Cost** (April 1984), is deleted in its entirety and FAR Clause **52.232-22, Limitation Of Funds** (April 1984) is substituted therefor. **[NOTE: When this contract is fully funded, FAR Clause 52.232-22, LIMITATION OF FUNDS will no longer apply and FAR Clause 52.232-20, LIMITATION OF COST will become applicable.]**

ARTICLE I.3. ADDITIONAL CONTRACT CLAUSES

Additional clauses other than those listed below which are based on the type of contract/Contractor shall be determined during negotiations. Any contract awarded from this solicitation will contain the following:

This contract incorporates the following clauses by reference, (unless otherwise noted), with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available.

a. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES

1. FAR Clause **52.203-13, Contractor Code of Business Ethics and Conduct** (December 2007).
2. FAR Clause **52.203-14, Display of Hotline Poster(s)** (December 2007).

".....(3) Any required posters may be obtained as follows:

Poster(s)	Obtain From"
HHS Contractor Code of Ethics and Business Conduct Poster	http://www.oig.hhs.gov/hotline/OIG_Hotline_Poster.pdf

3. FAR Clause **52.204-9, Personal Identity Verification of Contractor Personnel** (September 2007).
4. FAR Clause **52.217-8, Option to Extend Services** (November 1999).

"..The Contracting Officer may exercise the option by written notice to the Contractor within 60 days..."
5. FAR Clause **52.219-4, Notice of Price Evaluation Preference for HUBZone Small Business Concerns** (July 2005).

"(c) Waiver of evaluation preference.....
 Offeror elects to waive the evaluation preference."
6. FAR Clause **52.219-25, Small Disadvantaged Business Participation Program--Disadvantaged Status and Reporting** (April 2008).
7. FAR Clause **52.227-19, Commercial Computer Software License** (December 2007).
8. FAR Clause **52.237-3, Continuity of Services** (January 1991).
9. FAR Clause **52.239-1, Privacy or Security Safeguards** (August 1996).
10. FAR Clause **52.242-3, Penalties for Unallowable Costs** (May 2001).

11. FAR Clause **52.248-1, Value Engineering** (February 2000).

12. FAR Clause **52.251-1, Government Supply Sources** (April 1984).

b. *DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) (48 CHAPTER 3) CLAUSES:*

1. *HHSAR Clause **352.224-70, Confidentiality of Information** (January 2006).*

c. *NATIONAL INSTITUTES OF HEALTH (NIH) RESEARCH CONTRACTING (RC) CLAUSES:*

The following clauses are attached and made a part of this contract:

1. ***NIH (RC)-7, Procurement of Certain Equipment** (April 1984).*

ARTICLE I.4. ADDITIONAL FAR CONTRACT CLAUSES INCLUDED IN FULL TEXT

Additional clauses other than those listed below which are based on the type of contract/Contractor shall be determined during negotiations. Any contract awarded from this solicitation will contain the following:

This contract incorporates the following clauses in full text.

FEDERAL ACQUISITION REGULATION (FAR)(48 CFR CHAPTER 1) CLAUSES:

a. **FAR Clause 52.222-39, Notification Of Employee Rights Concerning Payment Of Union Dues Or Fees (December 2004)**

(a) *Definition. As used in this clause --*

United States means the 50 States, the District of Columbia, Puerto Rico, the Northern Mariana Islands, American Samoa, Guam, the U.S. Virgin Islands, and Wake Island.

(b) *Except as provided in paragraph (e) of this clause, during the term of this contract, the Contractor shall post a notice, in the form of a poster, informing employees of their rights concerning union membership and payment of union dues and fees, in conspicuous places in and about all its plants and offices, including all places where notices to employees are customarily posted. The notice shall include the following information (except that the information pertaining to National Labor Relations Board shall not be included in notices posted in the plants or offices of carriers subject to the Railway Labor Act, as amended (45 U.S.C. 151-188)).*

Notice to Employees

Under Federal law, employees cannot be required to join a union or maintain membership in a union in order to retain their jobs. Under certain conditions, the law permits a union and an employer to enter into a union-security agreement requiring employees to pay uniform periodic dues and initiation fees. However, employees who are not union members can object to the use of their payments for certain purposes and can only be required to pay their share of union costs relating to collective bargaining, contract administration, and grievance adjustment.

If you do not want to pay that portion of dues or fees used to support activities not related to collective bargaining, contract administration, or grievance adjustment, you are entitled to an appropriate reduction in your payment. If you believe that you have been required to pay dues or fees used in part to support activities not related to collective bargaining, contract administration, or grievance adjustment, you may be entitled to a refund and to an appropriate reduction in future payments.

For further information concerning your rights, you may wish to contact the National Labor Relations Board (NLRB) either at one of its Regional offices or at the following address or toll free number:

*National Labor Relations Board
Division of Information
1099 14th Street, N.W.
Washington, DC 20570
1-866-667-6572
1-866-316-6572 (TTY)*

To locate the nearest NLRB office, see NLRB's website at <http://www.nlr.gov>.

(c) *The Contractor shall comply with all provisions of Executive Order 13201 of February 17, 2001, and related implementing regulations at 29 CFR part 470, and orders of the Secretary of Labor.*

(d) In the event that the Contractor does not comply with any of the requirements set forth in paragraphs (b), (c), or (g), the Secretary may direct that this contract be cancelled, terminated, or suspended in whole or in part, and declare the Contractor ineligible for further Government contracts in accordance with procedures at 29 CFR part 470, Subpart B--Compliance Evaluations, Complaint Investigations and Enforcement Procedures. Such other sanctions or remedies may be imposed as are provided by 29 CFR part 470, which implements Executive Order 13201, or as are otherwise provided by law.

(e) The requirement to post the employee notice in paragraph (b) does not apply to--

(1) Contractors and subcontractors that employ fewer than 15 persons;

(2) Contractor establishments or construction work sites where no union has been formally recognized by the Contractor or certified as the exclusive bargaining representative of the Contractor's employees;

(3) Contractor establishments or construction work sites located in a jurisdiction named in the definition of the United States in which the law of that jurisdiction forbids enforcement of union-security agreements;

(4) Contractor facilities where upon the written request of the Contractor, the Department of Labor Deputy Assistant Secretary for Labor-Management Programs has waived the posting requirements with respect to any of the Contractor's facilities if the Deputy Assistant Secretary finds that the Contractor has demonstrated that--

(i) The facility is in all respects separate and distinct from activities of the Contractor related to the performance of a contract; and

(ii) Such a waiver will not interfere with or impede the effectuation of the Executive order; or

(5) Work outside the United States that does not involve the recruitment or employment of workers within the United States.

(f) The Department of Labor publishes the official employee notice in two variations; one for contractors covered by the Railway Labor Act and a second for all other contractors. The Contractor shall--

(1) Obtain the required employee notice poster from the Division of Interpretations and Standards, Office of Labor-Management Standards, U.S. Department of Labor, 200 Constitution Avenue, NW, Room N-5605, Washington, DC 2021, or from any field office of the Department's Office of Labor-Management Standards or Office of Federal Contract Compliance Programs;

(2) Download a copy of the poster from the Office of Labor-Management Standards website at <http://www.olms.dol.gov>; or

(3) Reproduce and use exact duplicate copies of the Department of Labor's official poster.

(g) The Contractor shall include the substance of this clause in every subcontract or purchase order that exceeds the simplified acquisition threshold, entered into in connection with this contract, unless exempted by the Department of Labor Deputy Assistant Secretary for Labor-Management Programs on account of special circumstances in the national interest under authority of 29 CFR 470.3(c).

For indefinite quantity subcontracts, the Contractor shall include the substance of this clause if the value of orders in any calendar year of the subcontract is expected to exceed the simplified acquisition threshold. Pursuant to 29 CFR part 470, Subpart B--Compliance Evaluations, Complaint Investigations and Enforcement Procedures, the Secretary of Labor may direct the Contractor to take such action in the enforcement of these regulations, including the imposition of sanctions for noncompliance with respect to any such subcontract or purchase order. If the Contractor becomes

involved in litigation with a subcontractor or vendor, or is threatened with such involvement, as a result of such direction, the Contractor may request the United States, through the Secretary of Labor, to enter into such litigation to protect the interests of the United States.

(End of Clause)

PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

SECTION J - LIST OF ATTACHMENTS

The following documents are incorporated into this RFP:

SOLICITATION ATTACHMENTS

Attachment No.	Title	Location
Attachment 1:	Packaging and Delivery of Proposal (Non R & D)	Packaging_and_Delivery_of_Proposal.pdf
Attachment 2:	Proposal Intent Response Sheet	http://rcb.cancer.gov/rcb-internet/forms/intent.jsp Submit your proposal intent response sheets no later than August 14, 2008.
Attachment 3:	Statement of Work	SOW.pdf
Attachment 4:	Government Furnished Property	91000_Property.pdf
Attachment 5:	Quality Assurance Surveillance Plan	QASP_Award_Fee.pdf
Attachment 6:	Contractor Assessment Report/Performance Indicators and Standards	Contractor_Assessment_Report.pdf

TECHNICAL PROPOSAL ATTACHMENTS

Attachment No.	Title	Location
Attachment 7:	Summary of Related Activities	http://www.niaid.nih.gov/contract/forms.htm

BUSINESS PROPOSAL ATTACHMENTS

Attachment No.	Title	Location
Attachment 8:	Proposal Summary and Data Record, NIH-2043	http://www.niaid.nih.gov/contract/forms.htm
Attachment 9:	Small Business Subcontracting Plan	http://www.hhs.gov/osdbu/read/SampleSubcontractingPlan.doc
Attachment 10:	Breakdown of Proposed Estimated Costs (plus fee) w/Excel Spreadsheet	http://oamp.od.nih.gov/contracts/BUSCOST.HTM http://oamp.od.nih.gov/Division/DFAS/spshexcl.xls
Attachment 11:	Offeror's Points of Contact	http://www.niaid.nih.gov/contract/forms.htm
Attachment 12:	Certificate of Current Cost or Pricing Data	http://rcb.cancer.gov/rcb-internet/forms/cert-current-cost.pdf
Attachment 13:	Disclosure of Lobbying Activities, OMB Form SF-LLL	http://rcb.cancer.gov/rcb-internet/forms/sflllin.pdf

INFORMATIONAL ATTACHMENTS

Attachment No.	Title	Location
Attachment 14:	Monthly Summary Sheet of Sales	http://rcb.cancer.gov/rcb-internet/forms/monsales.pdf

Attachment No.	Title	Location
Attachment 15:	Invoice/Financing Request and Contract Financial Reporting Instructions--Cost Reimbursement, NIH(RC)-4	http://rcb.cancer.gov/rcb-internet/forms/rc4.pdf
Attachment 16:	Procurement of Certain Equipment, NIH(RC)-7	http://www.niaid.nih.gov/contract/forms/NIH-RC-7.pdf
Attachment 17:	Government Property Schedule	To be determined during negotiations.
Attachment 18:	Disclosure of Lobbying Activities, OMB Form SF-LLL	http://rcb.cancer.gov/rcb-internet/forms/sflllin.pdf
Attachment 19:	Commitment to Protect Non-Public Information Contractor Agreement	http://irm.cit.nih.gov/security/Nondisclosure.pdf
Attachment 20:	Roster of Employees Requiring Suitability Investigations	http://ais.nci.nih.gov/forms/Suitability-roster.xls
Attachment 21:	Employee Separation Checklist	http://rcb.cancer.gov/rcb-internet/forms/Emp-sep-checklist.pdf
Attachment 22:	Contract Performance Reports (EVM)	<p>Format 1: Work Breakdown Structure</p> <p>http://www.dtic.mil/whs/directives/infomgt/forms/eforms/dd2734-1.pdf</p> <p>Format 2: Organizational Categories</p> <p>http://www.dtic.mil/whs/directives/infomgt/forms/eforms/dd2734-2.pdf</p> <p>Format 3: Baseline</p> <p>http://www.dtic.mil/whs/directives/infomgt/forms/eforms/dd2734-3.pdf</p> <p>Format 4: Staffing</p> <p>http://www.dtic.mil/whs/directives/infomgt/forms/eforms/dd2734-4.pdf</p> <p>Format 5: Explanations and Problem Analyses</p> <p>http://www.dtic.mil/whs/directives/infomgt/forms/eforms/dd2734-5.pdf</p>

PART IV - REPRESENTATIONS AND INSTRUCTIONS

SECTION K - REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS

IF YOU INTEND TO SUBMIT A PROPOSAL, YOU MUST :

1. Go to the Online Representations and Certifications Application (ORCA) at: <https://orca.bpn.gov/> and complete the Representations and Certifications; and
2. Complete, and include as part of your BUSINESS PROPOSAL, SECTION K which can be accessed electronically from the INTERNET at the following address:
<http://rcb.cancer.gov/rcb-internet/wkf/sectionk.pdf>

If you are unable to access this document electronically, you may request a copy from the Contracting Officer identified on the cover page of this solicitation.

SECTION L - INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS

1. GENERAL INFORMATION

a. **INSTRUCTIONS TO OFFERORS--COMPETITIVE ACQUISITION** [FAR Provision 52.215-1 (January 2006)]

(a) *Definitions. As used in this provision--*

"Discussions" are negotiations that occur after establishment of the competitive range that may, at the Contracting Officer's discretion, result in the offeror being allowed to revise its proposal.

"In writing", "writing", or "written" means any worded or numbered expression that can be read, reproduced, and later communicated, and includes electronically transmitted and stored information.

"Proposal modification" is a change made to a proposal before the solicitation's closing date and time, or made in response to an amendment, or made to correct a mistake at any time before award.

"Proposal revision" is a change to a proposal made after the solicitation closing date, at the request of or as allowed by a Contracting Officer as the result of negotiations.

"Time," if stated as a number of days, is calculated using calendar days, unless otherwise specified, and will include Saturdays, Sundays, and legal holidays. However, if the last day falls on a Saturday, Sunday, or legal holiday, then the period shall include the next working day.

(b) Amendments to solicitations. If this solicitation is amended, all terms and conditions that are not amended remain unchanged. Offerors shall acknowledge receipt of any amendment to this solicitation by the date and time specified in the amendment(s).

(c) Submission, modification, revision, and withdrawal of proposals.

(1) Unless other methods (e.g., electronic commerce or facsimile) are permitted in the solicitation, proposals and modifications to proposals shall be submitted in paper media in sealed envelopes or packages (i) addressed to the office specified in the solicitation, and (ii) showing the time and date specified for receipt, the solicitation number, and the name and address of the offeror. Offerors using commercial carriers should ensure that the proposal is marked on the outermost wrapper with the information in paragraphs (c)(1)(i) and (c)(1)(ii) of this provision.

(2) The first page of the proposal must show--

(i) The solicitation number;

(ii) The name, address, and telephone and facsimile numbers of the offeror (and electronic address if available);

(iii) A statement specifying the extent of agreement with all terms, conditions, and provisions included in the solicitation and agreement to furnish any or all items upon which prices are offered at the price set opposite each item;

(iv) Names, titles, and telephone and facsimile numbers (and electronic addresses if available) of persons authorized to negotiate on the offeror's behalf with the Government in connection with this solicitation; and

(v) Name, title, and signature of person authorized to sign the proposal. Proposals signed by an agent shall be accompanied by evidence of that agent's authority, unless that evidence has been previously furnished to the issuing office.

(3) Submission, modification, revision, and withdrawal of proposals.

(i) Offerors are responsible for submitting proposals, and any modifications or revisions, so as to reach the Government office designated in the solicitation by the time specified in the solicitation. If no time is specified in the solicitation, the time for receipt is 4:30 p.m., local time, for the designated Government office on the date that proposal or revision is due.

(ii) (A) Any proposal, modification, or revision received at the Government office designated in the solicitation after the exact time specified for receipt of offers is "late" and will not be considered unless it is received before award is made, the Contracting Officer determines that accepting the late offer would not unduly delay the acquisition; and--

(1) If it was transmitted through an electronic commerce method authorized by the solicitation, it was received at the initial point of entry to the Government infrastructure not later than 5:00 p.m. one working day prior to the date specified for receipt of proposals; or

(2) There is acceptable evidence to establish that it was received at the Government installation designated for receipt of offers and was under the Government's control prior to the time set for receipt of offers; or

(3) It is the only proposal received.

(B) However, a late modification of an otherwise successful proposal that makes its terms more favorable to the Government, will be considered at any time it is received and may be accepted.

(iii) Acceptable evidence to establish the time of receipt at the Government installation includes the time/date stamp of that installation on the proposal wrapper, other documentary evidence of receipt maintained by the installation, or oral testimony or statements of Government personnel.

(iv) If an emergency or unanticipated event interrupts normal Government processes so that proposals cannot be received at the office designated for receipt of proposals by the exact time specified in the solicitation, and urgent Government requirements preclude amendment of the solicitation, the time specified for receipt of proposals will be deemed to be extended to the same time of day specified in the solicitation on the first work day on which normal Government processes resume.

(v) Proposals may be withdrawn by written notice received at any time before award. Oral proposals in response to oral solicitations may be withdrawn orally. If the solicitation authorizes facsimile proposals, proposals may be withdrawn via facsimile received at any time before award, subject to the conditions specified in the provision at 52.215-5, Facsimile Proposals. Proposals may be withdrawn in person by an offeror or an authorized representative, if the identity of the person requesting withdrawal is established and the person signs a receipt for the proposal before award.

(4) Unless otherwise specified in the solicitation, the offeror may propose to provide any item or combination of items.

(5) Offerors shall submit proposals in response to this solicitation in English, unless otherwise permitted by the solicitation, and in U.S. dollars, unless the provision at FAR 52.225-17, Evaluation of Foreign Currency Offers, is included in the solicitation.

(6) Offerors may submit modifications to their proposals at any time before the solicitation closing date and time, and may submit modifications in response to an amendment, or to correct a mistake at any time before award.

(7) Offerors may submit revised proposals only if requested or allowed by the Contracting Officer.

(8) Proposals may be withdrawn at any time before award. Withdrawals are effective upon receipt of notice by the Contracting Officer.

(d) Offer expiration date. Proposals in response to this solicitation will be valid for the number of days specified on the solicitation cover sheet (unless a different period is proposed by the offeror).

(e) Restriction on disclosure and use of data.

(1) The proposal submitted in response to this request may contain data (trade secrets; business data, e.g., commercial information, financial information, and cost and pricing data; and technical data) which the offeror, including its prospective subcontractor(s), does not want used or disclosed for any purpose other than for evaluation of the proposal. The use and disclosure of any data may be so restricted; provided, that the Government determines that the data is not required to be disclosed under the Freedom of Information Act, 5 U.S.C. 552, as amended, and the offeror marks the cover sheet of the proposal with the following statements, specifying the particular portions of the proposal which are to be restricted:

Unless disclosure is required by the Freedom of Information Act, 5 U.S.C. 552, as amended, (the Act) as determined by Freedom of Information (FOI) officials of the Department of Health and Human Services, data contained in the portions of this proposal which have been specifically identified by page number, paragraph, etc. by the offeror as containing restricted information shall not be used or disclosed except for evaluation purposes.

The offeror acknowledges that the Department may not be able to withhold a record (data, document, etc.) nor deny access to a record requested pursuant to the Act and that the Department's FOI officials must make that determination. The offeror hereby agrees that the Government is not liable for disclosure if the Department has determined that disclosure is required by the Act.

If a contract is awarded to the offeror as a result of, or in connection with, the submission of this proposal, the Government shall have right to use or disclose the data to the extent provided in the contract. Proposals not resulting in a contract remain subject to the Act.

The offeror also agrees that the Government is not liable for disclosure or use of unmarked data and may use or disclose the data for any purpose, including the release of the information pursuant to requests under the Act. The data subject to this restriction are contained in pages (insert page numbers, paragraph designations, etc. or other identification).

(2) In addition, the offeror must mark each page of data it wishes to restrict with the following statement:

"Use or disclosure of data contained on this page is subject to the restriction on the cover sheet of this proposal or quotation."

(3) Offerors are cautioned that proposals submitted with restrictive statements or statements differing in substance from those cited above may not be considered for award. The Government reserves the right to reject any proposal submitted with a nonconforming statement(s).

(f) Contract award.

- (1) The Government intends to award a contract or contracts resulting from this solicitation to the responsible offeror(s) whose proposal(s) represents the best value after evaluation in accordance with the factors and subfactors in the solicitation.*
- (2) The Government may reject any or all proposals if such action is in the Government's interest.*
- (3) The Government may waive informalities and minor irregularities in proposals received.*
- (4) The Government intends to evaluate proposals and award a contract without discussions with offerors (except clarifications as described in FAR 15.306(a)). Therefore, the offeror's initial proposal should contain the offeror's best terms from a cost or price and technical standpoint. The Government reserves the right to conduct discussions if the Contracting Officer later determines them to be necessary. If the Contracting Officer determines that the number of proposals that would otherwise be in the competitive range exceeds the number at which an efficient competition can be conducted, the Contracting Officer may limit the number of proposals in the competitive range to the greatest number that will permit an efficient competition among the most highly rated proposals.*
- (5) The Government reserves the right to make an award on any item for a quantity less than the quantity offered, at the unit cost or prices offered, unless the offeror specifies otherwise in the proposal.*
- (6) The Government reserves the right to make multiple awards if, after considering the additional administrative costs, it is in the Government's best interest to do so.*
- (7) Exchanges with offerors after receipt of a proposal do not constitute a rejection or counteroffer by the Government.*
- (8) The Government may determine that a proposal is unacceptable if the prices proposed are materially unbalanced between line items or subline items. Unbalanced pricing exists when, despite an acceptable total evaluated price, the price of one or more contract line items is significantly overstated or understated as indicated by the application of cost or price analysis techniques. A proposal may be rejected if the Contracting Officer determines that the lack of balance poses an unacceptable risk to the Government.*
- (9) If a cost realism analysis is performed, cost realism may be considered by the source selection authority in evaluating performance or schedule risk.*
- (10) A written award or acceptance of proposal mailed or otherwise furnished to the successful offeror within the time specified in the proposal shall result in a binding contract without further action by either party.*
- (11) If a post-award debriefing is given to requesting offerors, the Government shall disclose the following information, if applicable:*

 - (i) The agency's evaluation of the significant weak or deficient factors in the debriefed offeror's offer.*
 - (ii) The overall evaluated cost or price and technical rating of the successful and debriefed offeror and past performance information on the debriefed offeror.*
 - (iii) The overall ranking of all offerors, when any ranking was developed by the agency during source selection;*
 - (iv) A summary of the rationale for award.*

(v) *For acquisitions of commercial items, the make and model of the item to be delivered by the successful offeror.*

(vi) *Reasonable responses to relevant questions posed by the debriefed offeror as to whether source-selection procedures set forth in the solicitation, applicable regulations, and other applicable authorities were followed by the agency.*

(End of Provision)

Alternate I (October 1997). As prescribed in 15.209(a)(1), substitute the following paragraph (f)(4) for paragraph (f)(4) of the basic provision:

(f) (4) The Government intends to evaluate proposals and award a contract after conducting discussions with offerors whose proposals have been determined to be within the competitive range. If the Contracting Officer determines that the number of proposals that would otherwise be in the competitive range exceeds the number at which an efficient competition can be conducted, the Contracting Officer may limit the number of proposals in the competitive range to the greatest number that will permit an efficient competition among the most highly rated proposals. Therefore, the offeror's initial proposal should contain the offeror's best terms from a price and technical standpoint.

b. NAICS CODE AND SIZE STANDARD

Note: The following information is to be used by the offeror in preparing its Representations and Certifications (See Section K of this RFP), specifically in completing the provision entitled, SMALL BUSINESS PROGRAM REPRESENTATION, FAR Clause 52.219-1.

1. The North American Industry Classification System (NAICS) code for this acquisition is 541513.
2. The small business size standard is 23 M.

THIS REQUIREMENT IS NOT SET-ASIDE FOR SMALL BUSINESS. However, the Federal Acquisition Regulation (FAR) requires in every solicitation, (except for foreign acquisitions) the inclusion of the North American Industry Classification System (NAICS) Code and corresponding size standard which best describes the nature of the requirement in the solicitation.

c. TYPE OF CONTRACT AND NUMBER OF AWARDS

It is anticipated that one award will be made from this solicitation and that the award will be made on November 1, 2008.

It is anticipated that the award from this solicitation will be a multiple-year Cost-Reimbursement type Completion contract with a Period of Performance of three (3) years with four (4) Award Term years, and that incremental funding will be used (See Section L.2.c. Business Proposal Instructions).

d. PERFORMANCE BASED ACQUISITION

The Government intends to use a Performance Based Acquisition method in the evaluation and award of any contract resulting from this RFP.

The Performance Based contract is designed to motivate the Contractor to perform at a higher standard. Outstanding performance is rewarded through an incentive defined in the contract. The following performance incentive will be used in any contract awarded from this RFP:

Cost-Plus-Award-Fee (CPAF): The CPAF contract includes an estimated cost and an award fee amount that is paid based upon periodic evaluations of Contractor performance. The Quality Assurance Surveillance Plan (QASP), which is included as an attachment to this RFP sets forth

all the elements required for evaluation and determination of the award fee amount. The award fee determination is made unilaterally by the Government and is not subject to Disputes clause procedures. The QASP is included in this RFP and located at SECTION J.

AND

Award Term (AT): The AT contract includes one or more extensions of the contract period for which the Contractor is entitled based upon periodic evaluations of Contractor performance. This is not a Government option to extend the contract. Under the Award Term incentive, if the Contractor's evaluated performance meets the Award Term criteria set forth in the Quality Assurance Surveillance Plan (QASP), the Award Term must be issued. The QASP is included in this RFP and located at Section J.

e. ESTIMATE OF EFFORT

The Government estimates that the work set forth in the Statement of Work of this solicitation will require approximately 117,760 labor hours per year over the seven years of the contract. It is further estimated that if the option for IPAD development is exercised, 4,320 labor hours per year will be required over the two years estimated for this option.

Offerors should use the estimate that the CTEP-ESYS will contain approximately 15,000 user accounts with approximately 1,500 users. It is estimated that 4,000 help desk requests of varying complexity will occur annually. In 2007, CTEP entered data into CTEP-ESYS on approximately 2,000 protocol documents and compiled and coordinated 230 special mailings to investigators related to adverse events affecting approximately 5,500 protocols.

f. COMMITMENT OF PUBLIC FUNDS

The Contracting Officer is the only individual who can legally commit the Government to the expenditure of public funds in connection with the proposed procurement. Any other commitment, either explicit or implied, is invalid.

g. COMMUNICATIONS PRIOR TO CONTRACT AWARD

Offerors shall direct all communications to the attention of the Contract Specialist or Contracting Officer cited on the face page of this RFP. Communications with other officials may compromise the competitiveness of this acquisition and result in cancellation of the requirement.

h. RELEASE OF INFORMATION

Contract selection and award information will be disclosed to offerors in accordance with regulations applicable to negotiated acquisition. Prompt written notice will be given to unsuccessful offerors as they are eliminated from the competition, and to all offerors following award.

i. REFERENCE MATERIALS

The Government will provide an online "reading room" of reference material pertinent to this acquisition on the CTEP web page <http://ctep.cancer.gov/guidelines/artifacts.html> . In addition, Offerors should refer to the Statement of Work , Appendix 3. Offerors are invited to visit the CTEP Home Page web site <http://ctep.cancer.gov> to obtain information about Informatics projects and their current status. Failure of offerors to examine the reference materials prior to proposal preparation and submission will be at the offeror's own risk. The Government will make available CTEP facilities for offerors that want to see the physical equipment, software and location for the work. This will be by appointment only. Contact Ms. Annmarie Keane, Contracting Officer, (301) 435-3814 for arrangements. Note: Contact Annmarie Keane no latter than August 8, 2008 to schedule an appointment.

j. PREPARATION COSTS

This RFP does not commit the Government to pay for the preparation and submission of a proposal.

k. SERVICE OF PROTEST (SEPTEMBER 2006) - FAR 52.233-2

(a) Protests, as defined in section 33.101 of the Federal Acquisition Regulation, that are filed directly with an agency, and copies of any protests that are filed with the Government Accountability Office (GAO), shall be served on the Contracting Officer (addressed as follows) by obtaining written and dated acknowledgment of receipt from:

Contracting Officer
Office of Acquisitions
National Cancer Institute
EPS, Room 6056
6120 EXECUTIVE BLVD MSC 7193
BETHESDA MD 20892- 7193

(b) The copy of any protest shall be received in the office designated above within one day of filing a protest with the GAO.

(End of Provision)

l. AVAILABILITY OF THE "FEDERAL ADP AND TELECOMMUNICATIONS STANDARDS INDEX."

Copies of the "Federal ADP and Telecommunications Standards Index" can be purchased from the U.S. Government Printing Office, Superintendent of Documents, Washington, DC 20402.

2. INSTRUCTIONS TO OFFERORS

a. GENERAL INSTRUCTIONS

INTRODUCTION

The following instructions will establish the acceptable minimum requirements for the format and contents of proposals. Special attention is directed to the requirements for technical and business proposals to be submitted in accordance with these instructions.

1. Contract Type and General Clauses

It is contemplated that a cost-reimbursement completion type award term contract will be awarded. (See General Information) Any resultant contract shall include the clauses applicable to the selected offeror's organization and type of contract awarded as required by Public Law, Executive Order, or acquisition regulations in effect at the time of execution of the proposed contract.

2. Authorized Official and Submission of Proposal

The proposal must be signed by an official authorized to bind your organization and must stipulate that it is predicated upon all the terms and conditions of this RFP. Your proposal shall be submitted in the number of copies, to the addressees, and marked as indicated in the Attachment entitled, PACKAGING AND DELIVERY OF PROPOSAL, Part III, Section J hereof. Proposals will be typewritten, paginated, reproduced on letter size paper and will be legible in all required copies. To expedite the proposal evaluation, all documents required for responding to the RFP should be placed in the following order:

I. COVER PAGE

Include RFP title, number, name of organization, DUNS No., identification of the proposal part, and indicate whether the proposal is an original or a copy.

II. TECHNICAL PROPOSAL

It is recommended that the technical proposal consist of a cover page, a table of contents, and the information requested in the Technical Proposal Instructions and as specified in SECTION J, List of Attachments.

III. BUSINESS PROPOSAL

It is recommended that the business proposal consist of a cover page, a table of contents, and the information requested in the Business Proposal Instructions and as specified in SECTION J, List of Attachments.

3. Proposal Summary and Data Record (NIH-2043)

The Offeror must complete the Form NIH-2043, attached, with particular attention to the length of time the proposal is firm and the designation of those personnel authorized to conduct negotiations. (See SECTION J, Attachment entitled, PROPOSAL SUMMARY AND DATA RECORD).

4. Separation of Technical and Business Proposals

The proposal must be prepared in two parts: a "Technical Proposal" and a "Business Proposal." Each of the parts shall be separate and complete in itself so that evaluation of one may be accomplished independently of, and concurrently with, evaluation of the other. The technical proposal should disclose your technical approach in as much detail as possible, including, but not limited to, the requirements of the technical proposal instructions.

5. Alternate Proposals

You may, at your discretion, submit alternate proposals, or proposals which deviate from the requirements; provided, that you also submit a proposal for performance of the work as specified in the statement of work. Such proposals may be considered if overall performance would be improved or not compromised and if they are in the best interests of the Government. Alternative proposals, or deviations from any requirements of this RFP, shall be clearly identified.

6. Evaluation of Proposals

The Government will evaluate technical proposals in accordance with the criteria set forth in PART IV, SECTION M of this RFP.

7. Use of the Metric System of Measurement

It is the policy of the Department of Health and Human Services to support the Federal transition to the metric system and to use the metric system of measurement in all procurements, grants, and other business related activities unless such use is impracticable or is likely to cause significant inefficiencies.

The offeror is encouraged to prepare their proposal using either "Hard Metric," "Soft Metric," or "Dual Systems" of measurement. The following definitions are provided for your information:

Hard Metric - - The replacement of a standard inch-pound size with an accepted metric size for a particular purpose. An example of size substitution might be: selling or packaging liquids by the liter instead of by the pint or quart (as for soft drinks), or instead of by the gallon (as for gasoline).

Soft Metric - The result of a mathematical conversion of inch-pound measurements to metric equivalents for a particular purpose. The physical characteristics are not changed.

Dual Systems - The use of both inch-pound and metric systems. For example, an item is designed, produced, and described in inch-pound values with soft metric values also shown for information or comparison purposes.

8. Privacy Act - Treatment of Proposal Information

The Privacy Act of 1974 (P.L. 93-579) requires that a Federal agency advise each individual whom it asks to supply information, the authority which authorizes the solicitation, whether disclosure is voluntary or mandatory, the principal purpose or purposes for which the information is intended to be used, the uses outside the agency which may be made of the information, and the effects on the individual, if any, of not providing all or any part of the requested information.

The NIH is requesting the information called for in this RFP pursuant to the authority provided by Sec. 301(a)(7) of the Public Health Service Act, as amended, and P.L. 92-218, as amended.

Providing the information requested is entirely voluntary. The collection of this information is for the purpose of conducting an accurate, fair, and adequate review prior to a discussion as to whether to award a contract.

Failure to provide any or all of the requested information may result in a less than adequate review.

In addition, the Privacy Act of 1974 (P.L. 93-579, Section 7) requires that the following information be provided when individuals are requested to disclose their social security number.

Provision of the social security number is voluntary. Social security numbers are requested for the purpose of accurate and efficient identification, referral, review and management of NIH contracting programs. Authority for requesting this information is provided by Section 301 and Title IV of the PHS Act, as amended.

The information provided by you may be routinely disclosed for the following purposes:

- to the cognizant audit agency and the Government Accountability Office for auditing.
- to the Department of Justice as required for litigation.
- to respond to congressional inquiries.
- to qualified experts, not within the definition of Department employees, for opinions as a part of the review process.

9. Selection of Offerors

- a. The acceptability of the technical portion of each contract proposal will be evaluated by a technical review committee. The committee will evaluate each proposal in strict conformity with the evaluation criteria of the RFP, utilizing point scores and written critiques. The committee may suggest that the Contracting Officer request clarifying information from an offeror.
- b. The business portion of each contract proposal will be subjected to a cost and price analysis, management analysis, etc.
- c. If award will be made without conducting discussions, offerors may be given the opportunity to clarify certain aspects of their proposal (e.g., the relevance of an offeror's past performance information and adverse past performance information to which the offeror has not previously had an opportunity to respond) or to resolve minor or clerical errors.
- d. If the Government intends to conduct discussions prior to awarding a contract -

1. Communications will be held with offerors whose past performance information is the determining factor preventing them from being placed within the competitive range. Such communications shall address adverse past performance information to which an offeror has not had a prior opportunity to respond. Also, communications may be held with any other offerors whose exclusion from, or inclusion in, the competitive range is uncertain.

Such communications shall not be used to cure proposal deficiencies or omissions that alter the technical or cost elements of the proposal, and/or otherwise revise the proposal, but may be considered in rating proposals for the purpose of establishing the competitive range.

2. The Contracting Officer will, in concert with program staff, decide which proposals are in the competitive range. The competitive range will be comprised of all of the most highly rated proposals. Oral or written discussions will be conducted with all offerors in the competitive range.

While it is NCI's policy to conduct discussions with all offerors in the competitive range, NCI reserves the right, in special circumstances, to limit the number of proposals included in the competitive range to the greatest number that will permit an efficient competition. All aspects of the proposals are subject to discussions, including cost, technical approach, past performance, and contractual terms and conditions. At the conclusion of discussions, each offeror still in the competitive range shall be given an opportunity to submit a written Final Proposal Revision (FPR) with the reservation of the right to conduct finalization of details with the selected source in accordance with HHSAR 315.370.

- e. The process described in FAR 15.101-1 will be employed, which permits the Government to make tradeoffs among cost or price and non-cost factors and to consider award to other than the lowest price offeror or other than the highest technically rated offeror.
- f. The NCI reserves the right to make a single award, multiple awards, or no award at all to the RFP. In addition, the RFP may be amended or canceled as necessary to meet NCI requirements. Synopses of awards exceeding \$25,000 will be published in FedBizOpps.

10. Past Performance Information

- a. Offerors shall submit the following information as part of their Business proposal.

A list of the last 3 contracts completed during the past Five years and THE LAST 5 CONTRACTS AWARDED currently being performed that are similar in nature to the solicitation workscope. Contracts listed may include those entered into by the Federal Government, agencies of state and local governments and commercial concerns. Offerors may also submit past performance information regarding predecessor companies, key personnel who have relevant experience or subcontractors that will perform major or critical aspects of the requirement when such information is relevant to the instant acquisition. For the purposes of this solicitation, a "major subcontract" is defined as greater than \$100,000.

Include the following information for each contract or subcontract listed:

1. Name of Contracting Organization
2. Contract Number (for subcontracts, provide the prime contract number and the subcontract number)
3. Contract Type
4. Total Contract Value
5. Description of Requirement
6. Contracting Officer's Name and Telephone Number

7. Program Manager's Name and Telephone Number
8. North American Industry Classification System (NAICS) Code

The offeror may provide information on problems encountered on the identified contracts and the offeror's corrective actions.

- b. The Government is not required to contact all references provided by the offeror. Also, references other than those identified by the offeror may be contacted by the Government to obtain additional information that will be used in the evaluation of the offeror's past performance.

11. **Electronic and Information Technology Accessibility, HHSAR 352.270-19(a) (January 2008)**

Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794D), as amended by the Workforce Investment Act of 1998, and the Architectural and Transportation Barriers Compliance Board Electronic and Information (EIT) Accessibility Provisions (36 CFR part 1194), require that, unless an exception applies, all EIT products and services developed, acquired, maintained, or used by any Federal department or agency permit:

1. Federal employees with disabilities to have access to and use information and data that is comparable to the access and use of information and data by Federal employees who are not individuals with disabilities; and
2. Members of the public with disabilities seeking information or services from a Federal agency to have access to and use of information and data that is comparable to the access and use of information and data by members of the public who are not individuals with disabilities.

Accordingly, any vendor submitting a proposal/quotations/bid in response to this solicitation must demonstrate compliance with the established EIT accessibility provisions. Information about Section 508 provisions is available at <http://www.section508.gov/>. The complete text of Section 508 Final Provisions can be accessed at <http://www.access-board.gov/sec508/provisions.htm>.

The Section 508 standards applicable to this solicitation are identified in the Statement of Work/ Specification/Performance Work Statement. In order to facilitate the Government's evaluation to determine whether EIT products and services proposed meet applicable Section 508 accessibility standards, offerors must prepare an HHS Section 508 Product Assessment Template, in accordance with its completion instructions, and provide a binding statement of conformance. The purpose of the template is to assist HHS acquisition and program officials in determining that EIT products and services proposed support applicable Section 508 accessibility standards. The template allows vendors or developers to self-evaluate their products or services and document in detail how they do or do not conform to a specific Section 508 standard. Instructions for preparing the HHS Section 508 Product Assessment Template may be found at <http://508.hhs.gov>.

Respondents to this solicitation must also provide any additional detailed information necessary for determining applicable Section 508 standards conformance, as well as for documenting EIT products and/or services that are incidental to the project, which would constitute an exception to Section 508 requirements. If a vendor claims its products and/or services, including EIT deliverables such as electronic documents and reports, meet applicable Section 508 standards in its completed HHS Section 508 Product Assessment Template, and it is later determined by the Government - i.e., after award of a contract/order, that products and/or services delivered do not conform to the described accessibility in the Product Assessment Template, remediation of the products and/or services to the level of conformance specified in the vendor's Product Assessment Template will be the responsibility of the Contractor at its expenses.

(End of provision)

12. **Solicitation Provisions Incorporated by Reference, FAR 52.252-1 (February 1998)**

This Solicitation incorporates one or more solicitation provisions by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. The offeror is cautioned that the listed provisions may include blocks that must be completed by the offeror and submitted with its quotation or offer. In lieu of submitting the full text provisions, the offeror may identify the provision by paragraph identifier and provide the appropriate information with its quotation or offer. Also, the full text of a solicitation provision may be accessed electronically at this address: <http://www.acquisition.gov/far/index.html>.

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1):

- a. Facilities Capital Cost of Money, FAR Clause 52.215-16, (October 1997).*
- b. Order of Precedence-Uniform Contract Format, FAR Clause 52.215-8, (October 1997).*
- c. Preaward On-Site Equal Opportunity Compliance Evaluation, (Over \$10,000,000), FAR Clause 52.222-24, (February 1999).*

b. TECHNICAL PROPOSAL INSTRUCTIONS

NOTE - CMMI Level III or higher is a Mandatory Qualification Criteria. This qualification criteria establishes conditions that must be met at the time of receipt of Proposals by the Contracting Officer in order for your proposal to be considered any further for award.

The Offeror must provide with the proposal a copy of the appraisal that certifies that it has achieved CMMI Level III or higher.

A detailed work plan must be submitted indicating how each aspect of the statement of work is to be accomplished. Your technical approach should be in as much detail as you consider necessary to fully explain your proposed technical approach or method. The technical proposal should reflect a clear understanding of the nature of the work being undertaken. The technical proposal must include information on how the project is to be organized, staffed, and managed. Information should be provided which will demonstrate your understanding and management of important events or tasks. **Note: The Government encourages offerors to be complete but succinct in the presentation and to limit the number of pages for each part of the proposal to the following:**

Technical Proposal: No more than 150 single sided pages using a 12 point font

Technical Proposal Attachments: No more than 50 single sided pages using a 12 point font

Note to Offerors: Beginning May 25, 2008, the offeror shall include the applicable PubMed Central (PMC) or NIH Manuscript Submission reference number when citing publications that arise from its NIH funded research.

1. Technical Discussions

The technical discussion included in the technical proposal should respond to the items set forth below:

a. Statement of Work

The proposal should include: 1) a statement of the overall objectives of the project, as envisaged by the offeror; and 2) an outline of the technical approach that would be used to achieve the objectives.

Proposals should address each area of the Statement of Work in a manner that describes the offeror's approach to the particular task and methods of quality control for the

various tasks outlined in the Statement of Work. The offeror should demonstrate a clear understanding of the needs of the program and an understanding of the potential problems involved with these types of projects.

Specifically, the offeror should discuss its:

- 1) Approach to specific technical aspects of investigational drug management and investigator registration.
- 2) Understanding of the needs of the project and understanding the FDA requirements as they relate to drug management and investigator registration.
- 3) Approach to and development of plans and documentation addressing:
 - i. Quality and change management
 - ii. System availability and functionality including disaster recovery
 - iii. Transition-in over a period of 90 days
 - iv. Earned Value Management - specifically, the offeror should describe the approach to EVM and provide a copy of the most recently developed EVM plan for a Tier I investment.
- 4) As part of the Technical Proposal, provide a detailed description of how the Contract performance will be maintained during fluctuations in the personnel needs as a result of high or low levels of requests, etc. Also explain in detail the plan for maintaining performance during periods of extended absences by personnel. For personnel proposed as "backup" personnel to key positions, Curriculum Vitae or resumes should be provided.
- 5) Provide a plan on how you will be able to bring on new staff if the options proposed for this contract are exercised.
- 6) The Government will provide the hardware and software as listed in the Government Property attachment.

b. Personnel

Describe the experience, qualifications and availability of all personnel who will be assigned for direct work on this project. Information is required which shows the composition of the task or work group, its general qualifications and recent experience with similar programs. Each area of the Statement of Work shall be addressed in sufficient detail to permit evaluation of the proposal in terms of the adequacy and availability, as needed, of all staff to be assigned to the project. Indicate the approximate percentage of total time each could be made available for this contract and specifically to which tasks each employee would be assigned.

Within the total level of effort offerors should indicate the specific level of effort which they consider appropriate for each function outlined in the Statement of Work. Provide a Personnel Ranking Matrix which indicates the hierarchical line of supervisory authority, and indicate which contractor employee(s) will perform the various tasks. State the estimated time to be spent on the project.

OFFERORS SHOULD ASSURE THAT THE PRINCIPAL INVESTIGATOR, AND ALL OTHER PERSONNEL PROPOSED, SHALL NOT BE COMMITTED ON FEDERAL GRANTS AND CONTRACTS FOR MORE THAN A TOTAL OF 100% OF THEIR TIME. IF THE SITUATION ARISES WHERE IT IS DETERMINED THAT A PROPOSED EMPLOYEE IS COMMITTED FOR MORE THAN 100% OF HIS OR HER TIME, THE GOVERNMENT WILL REQUIRE ACTION ON THE PART OF THE OFFEROR TO CORRECT THE TIME COMMITMENT.

1. Project Manager

List the name of the Project Manager responsible for the overall implementation and management of the contract and the offeror's key contact for technical aspects of the program. The Project Manager shall be an employee of the offeror and not a consultant or subcontractor. He/she shall have authority to commit company resources as needed for efficient and timely completion of work under this contract.

The Project Manager should possess at least a bachelors degree in health care, computer sciences, business or related discipline plus three (or more) years management experience in the health care/bioinformatics/biomedical/clinical research field. He/she should demonstrate experience within the oncology community and clinical trials. He/she should possess overall management capabilities which would permit effective implementation of all phases of the project. He/she should have experience in supervising all efforts of the type to be conducted under the contract. The individual should possess knowledge of quality control and assurance methods for all contract activities. The CV of the individual should include all certifications earned such as project management, quality improvement, database development, etc. The Project Manager will coordinate all contractor activities pertaining to the work specified in the SOW.

This individual should demonstrate self motivation and demonstrate superior project management, communication, organization and analytical skills. This individual should demonstrate the ability to be able to converse with health care professionals at all levels using both verbal and written communication skills. He/she should have experience with word processing and spread sheet software/computer skills. He/she should demonstrate the ability to effectively present complex IT matters to non-IT persons in layman's terms.

2. Other Investigators

List all other professional personnel who will be participating in the project. Discuss the qualifications, experience, and accomplishments. State the estimated time each will spend on the project, proposed duties on the project, and the areas or phases for which each will be responsible.

3. Additional Personnel

List names, titles, and proposed duties of additional personnel, if any, who will be required for full-time employment, or on a subcontract or consultant basis. The technical areas, character, and extent of subcontract or consultant activity will be indicated and the anticipated sources will be specified and qualified. For all proposed personnel who are not currently members of the offeror's staff, a letter of commitment or other evidence of availability is required. A resume does not meet this requirement. Commitment letters for use of consultants and other personnel to be hired must include:

- The specific items or expertise they will provide.
- Their availability to the project and the amount of time anticipated.
- Willingness to act as a consultant.
- How rights to publications and patents will be handled.

4. Resumes

Resumes of all key personnel are required. Each must indicate educational background, recent experience, specific or technical accomplishments, and a listing of relevant publications.

2. A. Other Considerations

Record and discuss specific factors not included elsewhere which support your proposal. Using specifically titled subparagraphs, items may include:

- a. Any agreements and/or arrangements with subcontractor(s). Provide as much detail as necessary to explain how the statement of work will be accomplished within this working relationship.
- b. Unique arrangements, equipment, etc., which none or very few organizations are likely to have which is advantageous for effective implementation of this project.
- c. Equipment and unusual operating procedures established to protect personnel from hazards associated with this project.
- d. Other factors you feel are important and support your proposed research.
- e. Recommendations for changing reporting requirements if such changes would be more compatible with the offeror's proposed schedules.

B. Organizational Experience/Support Capabilities

Offerors shall describe in detail prior experience of the organization in furnishing services similar to each area described in the Statement of work. The proposal should include sufficient information to demonstrate the previous effectiveness of the firm in similar or related work. Include documentation with specific reference to applicable contract numbers, dates of agreements and dollar volume. This documentation should include clear and concise descriptions of these projects and should indicate project sponsors (e.g., government contract or grant, etc.). For each of the described projects, references (including phone numbers) should be provided. Please note that organizational experience is defined as accomplishment of work, either past or ongoing that is comparable or related to the effort required by this RFP. Organization experience should also specify the size and scope of the project referenced and if the offerer served as the prime or subcontractor. This includes overall offeror or corporate experience, but not the experience and/or past performance of individuals who are proposed as personnel involved with the Statement of Work in the RFP. Offerors should demonstrate experience with clinical trials including but not limited to scientific development activities, informatics supporting development processes, regulatory support efforts, and administrative/operations efforts.

The relationship of the proposed working group within the offeror's organizational structure should be described as well as how this relationship may facilitate performance on this project. Information should be provided on how staff training needs will be met. Additionally, the offeror should explain how the corporate office and expertise will provide support to this project and to the proposed Project Manager. The offeror should explain how the organization will support the project manager in resolving problems or special situations.

The Government will provide space in CTEP's office in for up to two (2) Technical Support Specialists. The technical support specialists will help trouble shoot user issues with CTEP-ESYS, install new CTEP-ESYS, and assist users with the audio visual system. CTEP's audio visual system is currently comprised of the following components; Polycom votex phone, Tandberg codec 3000, Cineo projector.

The Offeror should demonstrate that its physical facilities are adequate to perform the statement of work. The Offeror should demonstrate that it has a training facility on-site capable of hosting of up to 15 people classroom style where each student has their own desktop with the access to appropriate software and applications relevant to the training to occur. It is estimated that on-site classroom

training may be conducted at the Offeror's training facility or other facility conveniently located to CTEP, approximately four times per year and up to four hours per training session. The Offeror will also be engaged in training CTEP-ESYS users via web sessions or at CTEP.

3. Technical Evaluation

Proposals will be technically evaluated in accordance with SECTION M - Evaluation Factors for Award of this solicitation.

4. Obtaining and Disseminating Biomedical Research Resources

As a public sponsor of biomedical research, the National Institutes of Health (NIH) has a dual interest in accelerating scientific discovery and facilitating product development. Intellectual property restrictions can stifle the broad dissemination of new discoveries and limit future avenues of research and product development. At the same time, reasonable restrictions on the dissemination of research tools are sometimes necessary to protect legitimate proprietary interests and to preserve incentives for commercial development. To assist NIH contractors achieve an appropriate balance, the NIH has provided guidance in the form of a two-part document, consisting of Principles setting forth the fundamental concepts and Guidelines that provide specific information to patent and license professionals and sponsored research administrators for implementation.

The purpose of these Principles and Guidelines is to assist NIH funding recipients in determining: 1) Reasonable terms and conditions for making NIH-funded research resources available to scientists in other institutions in the public and private sectors (disseminating research tools); and 2) Restrictions to accept as a condition of receiving access to research tools for use in NIH-funded research (acquiring research tools). The intent is to help recipients ensure that the conditions they impose and accept on the transfer of research tools will facilitate further biomedical research, consistent with the requirements of the Bayh-Dole Act and NIH funding policy.

This policy, entitled, "Sharing Biomedical Research Resources: Principles and Guidelines for Recipients of NIH Research Grants and Contracts," (Federal Register Notice, December 23, 1999 [64 FR 72090]) will be included in any contract awarded from this solicitation. It can be found at the following website:

<http://ott.od.nih.gov/NewPages/64FR72090.pdf>

5. **Information Security** is applicable to this solicitation and the following information is provided to assist in proposal preparation.

IMPORTANT NOTE TO OFFERORS: The following information shall be addressed in a separate section of the Technical Proposal entitled, "INFORMATION SECURITY."

The Federal Information Security Management Act of 2002 (P.L. 107-347) (FISMA) requires each agency to develop, document, and implement an agency-wide information security program to safeguard information and information systems that support the operations and assets of the agency, including those provided or managed by another agency, contractor (including subcontractor), or other source. The National Institute of Standards and Technology (NIST) has issued a number of publications that provide guidance in the establishment of minimum security controls for management, operational and technical safeguards needed to protect the confidentiality, integrity and availability of a Federal information system and its information.

The Statement of Work (SOW) requires the successful offeror to (1) develop, (2) have the ability to access, or (3) host and/or maintain a Federal information system(s). Pursuant to Federal and HHS Information Security Program Policies the following requirements apply to this solicitation:

Federal Information Security Management Act of 2002 (FISMA), Title III, E-Government Act of 2002, Pub. L. No. 107-347 (Dec. 17, 2002); <http://csrc.nist.gov/drivers/documents/FISMA-final.pdf>

a. Information Type

Administrative, Management and Support Information:

Mission Based Information:

D.19.1 Scientific and technical research and innovation

D.20.1 Research and Development Information

b. Security Categories and Levels

Confidentiality Level: Low Moderate High
 Integrity Level: Low Moderate High
 Availability Level: Low Moderate High
Overall Level: Low Moderate High

c. Position Sensitivity Designations

Prior to award, the Government will determine the position sensitivity designation for each Contractor (including subcontractor) employee that the successful offeror proposes for work under the contract. For proposal preparation purposes, the following designations apply:

Level 6: Public Trust - High Risk (Requires Suitability Determination with a BI). Contractor employees assigned to a Level 6 position are subject to a Background Investigation (BI).

Level 5: Public Trust - Moderate Risk (Requires Suitability Determination with NACIC, MBI or LBI). Contractor employees assigned to a Level 5 position with no previous investigation and approval shall undergo a National Agency Check and Inquiry Investigation plus a Credit Check (NACIC), a Minimum Background Investigation (MBI), or a Limited Background Investigation (LBI)

Level 1: Non Sensitive (Requires Suitability Determination with an NACI). Contractor employees assigned to a Level 1 position are subject to a National Agency Check and Inquiry Investigation (NACI).

Upon award, the Contractor will be required to submit a roster of all staff (including subcontractor staff) working under the contract who will develop, have the ability to access, or host and/or maintain a federal information system(s). The Government will determine and notify the Contractor of the appropriate level of suitability investigation required for each staff member. An electronic template, "Roster of Employees Requiring Suitability Investigations," is available for Contractor use at: <http://ais.nci.nih.gov/forms/Suitability-roster.xls>

Upon receipt of the Government's notification of applicable Suitability Investigations required, the Contractor shall complete and submit the required forms within 30 days of the notification. Additional submission instructions can be found at the "NCI Information Technology Security Policies, Background Investigation Process" website: <http://ais.nci.nih.gov>.

Contractor/Subcontractor employees who have met investigative requirements within the past five years may only require an updated or upgraded investigation.

d. Information Security Training

HHS policy requires Contractors/Subcontractors receive security training commensurate with their responsibilities for performing work under the terms and conditions of their contractual agreements.

The successful offeror will be responsible for assuring that each Contractor/Subcontractor employee has completed the NIH Computer Security Awareness Training course at: <http://irtsectraining.nih.gov/> prior to performing any contract work, and thereafter completing the NIH-specified fiscal year refresher course during the period of performance of the contract. The successful offeror shall maintain a listing of all individuals who have completed this training and shall submit this listing to the Project Officer.

Additional security training requirements commensurate with the position may be required as defined in NIST Special Publication 800-16, Information Technology Security Training Requirements (<http://csrc.nist.gov/publications/nistpubs/800-16/800-16.pdf>). This document provides information about information security training that may be useful to potential offerors.

e. Offeror's Official Responsible for Information Security

The offeror shall include in the "Information Security" part of its Technical Proposal the name and title of its official who will be responsible for all information security requirements should the offeror be selected for an award.

f. NIST SP 800 53 Self Assessment

The offeror must include in the "Information Security" part of its Technical Proposal, a completed Self-Assessment required by NIST Draft SP 800-53, Recommended Security Controls for Federal Information Systems. (<http://csrc.nist.gov/publications> - under Special Publications).

Subcontracts: The offeror must include similar information for any proposed subcontractor that will perform under the SOW to (1) develop a Federal information system(s) at the offeror's/subcontractor's facility, or (2) host and/or maintain a Federal information system(s) at the offeror's/subcontractor's facility.

g. Draft Information System Security Plan

The offeror must include a draft Information System Security Plan (ISSP) using the current template in Appendix A of NIST SP 800 18, Guide to Developing Security Plans for Federal Information Systems (<http://csrc.nist.gov/publications/nistpubs/800-18-Rev1/sp800-18-Rev1-final.pdf>). The details contained in the offeror's draft ISSP must be commensurate with the size and complexity of the requirements of the SOW based on the System Categorization determined above in subparagraph (b) Security Categories and Levels.

Subcontracts: The offeror must include similar information for any proposed subcontractor that will perform under the SOW with the offeror whenever the submission of an ISSP is required.

Note to Offeror: The resultant contract will require the draft ISSP to be finalized in coordination with the Project Officer no later than 90 calendar days after contract award.

Also, a contractor is required to update and resubmit its ISSP to NIH every three years following award or when a major modification has been made to its internal system.

h. Common Security Configurations

The contractor shall ensure that any information technology acquired under this contract incorporates the applicable common security configuration established by the National Institute of Standards and Technology (NIST) at <http://checklists.nist.gov>.

i. References

1. Federal Information Security Management Act of 2002 (FISMA), Title III, E-Government Act of 2002, Pub. L. No. 107-347 (Dec. 17, 2002); <http://csrc.nist.gov/drivers/documents/FISMA-final.pdf>
2. DHHS Personnel Security/Suitability Handbook: <http://www.hhs.gov/ohr/manual/pssh.pdf>
3. NIH Computer Security Awareness Training Course: <http://irtsectraining.nih.gov/>

The following NIST publications may be found at the following site: <http://csrc.nist.gov/publications/>

[Note: The search tool on the left side of this page provides easy access to the documents.]

4. NIST Special Publication 800-16, Information Technology Security Training Requirements; and Appendix A-D
5. NIST SP 800-18, Guide for Developing Security Plans for Information Technology Systems
6. NIST SP 800-26, Revision 1, Computer Security
7. NIST SP 800-53, Revision 1, Recommended Security Controls for Federal Information Systems
8. NIST SP 800-60, Guide for Mapping Types of Information and Information Systems to Security Categories, Volume I; and Volume II, Appendices to Guide For Mapping Types of Information and Information Systems To Security Categories, Appendix C, and Appendix D
9. NIST SP 800-64, Security Considerations in the Information System Development Life Cycle
10. FIPS PUB 199, Standards for Security Categorization of Federal Information and Information Systems
11. FIPS PUB 200, Minimum Security Requirements for Federal Information and Information Systems

c. BUSINESS PROPOSAL INSTRUCTIONS

1. Basic Cost/Price Information

The business proposal must contain sufficient information to allow the Government to perform a basic analysis of the proposed cost or price of the work. This information shall include the amounts of the basic elements of the proposed cost or price. These elements will include, as applicable, direct labor,

fringe benefits, travel, materials, subcontracts, purchased parts, shipping, indirect costs and rate, fee, and profit.

2. Cost and Pricing Data

1. General Instructions

A. You must provide the following information on the first page of your pricing proposal:

1. Solicitation, contract, and/or modification number;
2. Name and address of offeror;
3. Name and telephone number of point of contact;
4. Name of contract administration office (if available);
5. Type of contract action (that is, new contract, change order, price revision/redetermination, letter contract, unpriced order, or other);
6. Proposed cost; profit or fee; and total;
7. Whether you will require the use of Government property in the performance of the contract, and, if so, what property. See Item (13) Other Administrative Data, subparagraph (2) Government Property of this Section L.2.c of this solicitation.;
8. Whether your organization is subject to cost accounting standards; whether your organization has submitted a CASB Disclosure Statement, and if it has been determined adequate; whether you have been notified that you are or may be in noncompliance with your Disclosure Statement or CAS, and, if yes, an explanation; whether any aspect of this proposal is inconsistent with your disclosed practices or applicable CAS, and, if so, an explanation; and whether the proposal is consistent with your established estimating and accounting principles and procedures and FAR Part 31, Cost Principles, and, if not, an explanation;
9. The following statement: This proposal reflects our estimates and/or actual costs as of this date and conforms with the instructions in FAR 15.403 5(b)(1) and Table 15 2. By submitting this proposal, we grant the Contracting Officer and authorized representative(s) the right to examine, at any time before award, those records, which include books, documents, accounting procedures and practices, and other data, regardless of type and form or whether such supporting information is specifically referenced or included in the proposal as the basis for pricing, that will permit an adequate evaluation of the proposed price;
10. Date of submission; and
11. Name, title and signature of authorized representative.

B. In submitting your proposal, you must include an index, appropriately referenced, of all the cost or pricing data and information accompanying or identified in the proposal. In addition, you must annotate any future additions and/or revisions, up to the date of agreement on price, or an earlier date agreed upon by the parties, on a supplemental index.

C. As part of the specific information required, you must submit, with your proposal, cost or pricing data (that is, data that are verifiable and factual and otherwise as defined at FAR 15.401). You must clearly identify on your cover sheet that cost or pricing data are included as part of the proposal. In addition, you must submit with your proposal any information reasonably required to explain your estimating process, including

1. The judgmental factors applied and the mathematical or other methods used in the estimate, including those used in projecting from known data; and

2. The nature and amount of any contingencies included in the proposed price.
- D. You must show the relationship between contract line item prices and the total contract price. You must attach cost element breakdowns for each proposed line item, using the appropriate format prescribed in the "Formats for Submission of Line Item Summaries" section below (General Instructions, paragraph 3.) You must furnish supporting breakdowns for each cost element, consistent with your cost accounting system.
 - E. When more than one contract line item is proposed, you must also provide summary total amounts covering all line items for each element of cost.
 - F. Whenever you have incurred costs for work performed before submission of a proposal, you must identify those costs in your cost/price proposal.
 - G. If you have reached an agreement with Government representatives on use of forward pricing rates/factors, identify the agreement, include a copy, and describe its nature.
 - H. As soon as practicable after final agreement on price or an earlier date agreed to by the parties, but before the award resulting from the proposal, you must, under the conditions stated in FAR 15.406 2, submit a Certificate of Current Cost or Pricing Data.

2. Cost Elements

Depending on your system, you must provide breakdowns for the following basic cost elements, as applicable:

- A. **Materials and services.** Provide a consolidated priced summary of individual material quantities included in the various tasks, orders, or contract line items being proposed and the basis for pricing (vendor quotes, invoice prices, etc.). Include raw materials, parts, components, assemblies, and services to be produced or performed by others. For all items proposed, identify the item and show the source, quantity, and price. Conduct price analyses of all subcontractor proposals. Conduct cost analyses for all subcontracts when cost or pricing data are submitted by the subcontractor. Include these analyses as part of your own cost or pricing data submissions for subcontracts expected to exceed the appropriate threshold in FAR 15.403 4. Submit the subcontractor cost or pricing data as part of your own cost or pricing data as required in paragraph 2.A(2) of this table. These requirements also apply to all subcontractors if required to submit cost or pricing data.
 1. *Adequate Price Competition.* Provide data showing the degree of competition and the basis for establishing the source and reasonableness of price for those acquisitions (such as subcontracts, purchase orders, material order, etc.) exceeding, or expected to exceed, the appropriate threshold set forth at FAR 15.403 4 priced on the basis of adequate price competition. For interorganizational transfers priced at other than the cost of comparable competitive commercial work of the division, subsidiary, or affiliate of the contractor, explain the pricing method (see FAR 31.205 26(e)).
 2. *All Other.* Obtain cost or pricing data from prospective sources for those acquisitions (such as subcontracts, purchase orders, material order, etc.) exceeding the threshold set forth in FAR 15.403 4 and not otherwise exempt, in accordance with FAR 15.403 1(b) (i.e., adequate price competition, commercial items, prices set by law or regulation or waiver). Also provide data showing the basis for establishing source and reasonableness of price. In addition, provide a summary of your cost analysis and a copy of cost or pricing data submitted by the prospective source in support of each subcontract, or purchase order that is the lower of either \$11.5 million or more, or both more than the pertinent cost or pricing data threshold and more than 10 percent of the prime contractor's proposed price. The Contracting Officer may require you to submit cost or pricing data in support of proposals in lower amounts. Subcontractor cost or pricing data must be accurate, complete and current as of the date of final price agreement, or an earlier date agreed upon by the parties, given on the prime

contractor's Certificate of Current Cost or Pricing Data. The prime contractor is responsible for updating a prospective subcontractor's data. For standard commercial items fabricated by the offeror that are generally stocked in inventory, provide a separate cost breakdown, if priced based on cost. For interorganizational transfers priced at cost, provide a separate breakdown of cost elements. Analyze the cost or pricing data and submit the results of your analysis of the prospective source's proposal. When submission of a prospective source's cost or pricing data is required as described in this paragraph, it must be included along with your own cost or pricing data submission, as part of your own cost or pricing data. You must also submit any other cost or pricing data obtained from a subcontractor, either actually or by specific identification, along with the results of any analysis performed on that data.

- B. **Direct Labor.** Provide a time phased (e.g., monthly, quarterly, etc.) breakdown of labor hours, rates, and cost by appropriate category, and furnish bases for estimates.
- C. **Indirect Costs.** Indicate how you have computed and applied your indirect costs, including cost breakdowns. Show trends and budgetary data to provide a basis for evaluating the reasonableness of proposed rates. Indicate the rates used and provide an appropriate explanation.
- D. **Other Costs.** List all other costs not otherwise included in the categories described above (e.g., special tooling, travel, computer and consultant services, preservation, packaging and packing, spoilage and rework, and Federal excise tax on finished articles) and provide bases for pricing.
- E. **Royalties.** If royalties exceed \$1,500, you must provide the following information on a separate page for each separate royalty or license fee:
 - 1. Name and address of licensor.
 - 2. Date of license agreement.
 - 3. Patent numbers.
 - 4. Patent application serial numbers, or other basis on which the royalty is payable.
 - 5. Brief description (including any part or model numbers of each contract item or component on which the royalty is payable).
 - 6. Percentage or dollar rate of royalty per unit.
 - 7. Unit price of contract item.
 - 8. Number of units.
 - 9. Total dollar amount of royalties.
 - 10. If specifically requested by the Contracting Officer, a copy of the current license agreement and identification of applicable claims of specific patents (see FAR 27.204 and 31.205 37).
- F. **Facilities Capital Cost of Money.** When you elect to claim facilities capital cost of money as an allowable cost, you must submit Form CASB CMF and show the calculation of the proposed amount (see FAR 31.205 10).

3. **Formats for Submission of Line Item Summaries**

The detailed breakdown shall be in the format as shown on the form **Breakdown of Proposed Estimated Cost (plus fee) and Labor Hours** (Section J, List of Attachments). For each separate cost estimate, the offeror must furnish a breakdown by cost element as indicated above. In addition, summary total amounts shall be furnished. In the event the RFP cites specific line items, by number, a cost breakdown for each line item must be furnished.

4. General Information

- a. There is a clear distinction between submitting cost or pricing data and merely making available books, records, and other documents without identification. The requirement for submission of cost or pricing data is met when all accurate cost or pricing data reasonably available to the offeror have been submitted, either actually or by specific identification, to the Contracting Officer or an authorized representative. As later information comes into your possession, it should be submitted promptly to the Contracting Officer in a manner that clearly shows how the information relates to the offeror's price proposal. The requirement for submission of cost or pricing data continues up to the time of agreement on price, or an earlier date agreed upon between the parties if applicable.
- b. By submitting your proposal, you grant the Contracting Officer or an authorized representative the right to examine records that formed the basis for the pricing proposal. That examination can take place at any time before award. It may include those books, records, documents, and other types of factual information (regardless of form or whether the information is specifically referenced or included in the proposal as the basis for pricing) that will permit an adequate evaluation of the proposed price.

3. **Requirements for Cost or Pricing Data or Information Other than Cost and Pricing Data [FAR Clause 52.215-20 (October 1997)]**

(a) Exceptions from cost or pricing data.

(1) In lieu of submitting cost or pricing data, offerors may submit a written request for exception by submitting the information described in the following subparagraphs. The Contracting Officer may require additional supporting information, but only to the extent necessary to determine whether an exception should be granted, and whether the price is fair and reasonable.

(i) Identification of the law or regulation establishing the price offered. If the price is controlled under law by periodic rulings, reviews, or similar actions of a governmental body, attach a copy of the controlling document, unless it was previously submitted to the contracting office.

(ii) Commercial item exception. For a commercial item exception, the offeror shall submit, at a minimum, information on prices at which the same item or similar items have previously been sold in the commercial market that is adequate for evaluating the reasonableness of the price for this acquisition. Such information may include

(A) For catalog items, a copy of or identification of the catalog and its date, or the appropriate pages for the offered items, or a statement that the catalog is on file in the buying office to which the proposal is being submitted. Provide a copy or describe current discount policies and price lists (published or unpublished), e.g., wholesale, original equipment manufacturer, or reseller. Also explain the basis of each offered price and its relationship to the established catalog price, including how the proposed price relates to the price of recent sales in quantities similar to the proposed quantities;

(B) For market priced items, the source and date or period of the market quotation or other basis for market price, the base amount, and applicable discounts. In addition, describe the nature of the market;

(C) For items included on an active Federal Supply Service Multiple Award Schedule contract, proof that an exception has been granted for the schedule item.

(2) The offeror grants the Contracting Officer or an authorized representative the right to examine, at any time before award, books, records, documents, or other directly pertinent records to verify any request for an exception under this provision, and the reasonableness of price. For items priced using catalog or market prices, or law or regulation, access does not extend to cost or profit information or other data relevant solely to the offeror's determination of the prices to be offered in the catalog or marketplace.

(b) Requirements for cost or pricing data. If the offeror is not granted an exception from the requirement to submit cost or pricing data, the following applies:

(1) The offeror shall prepare and submit cost or pricing data and supporting attachments in accordance with Table 15.2 of FAR 15.408.

(2) As soon as practicable after agreement on price, but before contract award (except for unpriced actions such as letter contracts), the offeror shall submit a Certificate of Current Cost or Pricing Data, as prescribed by FAR 15.406.2.

(End of provision)

Alternate I (October 1997) of FAR Clause **52.215-20, Requirements for Cost or Pricing Data or Information Other than Cost and Pricing Data** (October 1997). As prescribed in 15.408(l), **substitute the following paragraph (b)(1) for paragraph (b)(1) of the basic provision:**

(b)(1) The offeror shall submit cost or pricing data and supporting attachments in the following format:

The format specified in paragraph L.2.c.(4) Cost and Pricing Data, subparagraph 3. Formats for Submission of Line Item Summaries shall be used for the submission cost information. Submission of all other cost or pricing data shall be in accordance with Table 15-2 in FAR 15.408.

4. Small Business Subcontracting Plan

If the proposed contract exceeds a total estimated cost of \$550,000 for the entire period of performance, the offeror shall be required to submit an acceptable subcontracting plan in accordance with the terms of the clause entitled "Small Business Subcontracting Plan," FAR Clause No. 52.219-9, incorporated herein by reference in the Solicitation, See SECTION J - LIST OF ATTACHMENTS, BUSINESS PROPOSAL ATTACHMENTS of this RFP for an example of such a plan.

- a. THIS PROVISION DOES NOT APPLY TO SMALL BUSINESS CONCERNS.
- b. The term "subcontract" means any agreement (other than one involving an employer-employee relationship) entered into by a Federal Government prime Contractor or subcontractor calling for supplies or services required for the performance of the original contract or subcontract. This includes, but is not limited to, agreements/purchase orders for supplies and services such as equipment purchase, copying services, and travel services.
- c. The offeror understands that:
 1. No contract will be awarded unless and until an acceptable plan is negotiated with the Contracting Officer which plan will be incorporated into the contract, as a material part thereof.
 2. An acceptable plan must, in the determination of the Contracting Officer, provide the maximum practicable opportunity for Small Businesses, Small Disadvantaged Businesses, Women-Owned Small businesses, HUBZone Small Businesses, Veteran-Owned Small Businesses, and Service Disabled Veteran-Owned Small Businesses to participate in the performance of the contract.
 3. If a subcontracting plan acceptable to the Contracting Officer is not negotiated within the time limits prescribed by the contracting activity and such failure arises out of causes within

the control and with the fault or negligence of the offeror, the offeror shall be ineligible for an award. The Contracting Officer shall notify the Contractor in writing of the reasons for determining a subcontracting plan unacceptable early enough in the negotiation process to allow the Contractor to modify the plan within the time limits prescribed.

4. Prior compliance of the offeror with other such subcontracting plans under previous contracts will be considered by the Contracting Officer in determining the responsibility of the offeror for award of the contract.
 5. It is the offeror's responsibility to develop a satisfactory subcontracting plan with respect to Small Business Concerns, Small Disadvantaged Business Concerns, Women-Owned Small Business Concerns, HUBZone Small Business Concerns, Veteran-Owned Small Business Concerns, and Service Disabled Veteran-Owned Small Business Concerns that each such aspect of the offeror's plan will be judged independent of the other.
 6. The offeror will submit, as required by the Contracting Officer, subcontracting reports in accordance with the instructions thereon, and as further directed by the Contracting Officer. Subcontractors will also submit these reports to the Government's Contracting Officer or as otherwise directed, with a copy to the prime Contractor's designated small and disadvantaged business liaison.
- d. Each plan must contain the following:
1. Goals, expressed in terms of percentages of total planned subcontracting dollars, for the use of Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Business Concerns as subcontractors.
 2. A statement of total dollars planned to be subcontracted. A statement of total dollars to be subcontracted to each of the following type of small business concerns: Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses.
 3. A description of the principal types of supplies and services to be subcontracted with an identification of which supplies and services are expected to be subcontracted to Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned and/or Service Disabled Veteran-Owned Small Business Concerns.
 4. A description of the method used to develop the subcontracting goals.
 5. A description of the method used to identify potential sources for solicitation purposes.
 6. A statement as to whether or not indirect costs were included in establishing subcontracting goals. If they were, a description of the method used to determine the proportionate share of indirect costs to be incurred with Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses.
 7. The name of the individual employed by the offeror who will administer the offeror's subcontracting program and a description of his/her duties.
 8. A description of the efforts the offeror will make to assure that Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses have an equitable chance to compete for subcontracts.
 9. Assurances that the offeror will include in all subcontracts the contract clause "Utilization of Small Business Concerns." Assure that all subcontractors, other than small businesses, in excess of \$550,000 adopt a plan similar to the plan agreed upon by the offeror.
 10. Assurances that the offeror (and any required subcontractors) will cooperate in studies or surveys as required and submit required reports (Individual Subcontract Reports (ISRs) and Summary Subcontract Reports (SSRs) to the Government.

11. List the types of records the offeror will maintain to demonstrate procedures that have been adopted to comply with the requirement and goals in the plan, including establishing source lists. Also, the offeror shall describe its efforts to locate Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses and award subcontracts to them.

For additional information about each of the above elements required to be contained in the subcontracting plan, see FAR Clause 52.219-9, Small Business Subcontracting Plan, and the Sample Subcontracting Plan which is provided as an attachment to this RFP in SECTION J.

HHS expects each procuring activity to establish minimum subcontracting goals for all procurements. The anticipated minimum goals for this RFP are as follows:

27% for Small Business; 5% for Small Disadvantaged Business; 5% for Women-Owned Small Business; 3% for HUBZone Small Business; and 3% for Veteran-Owned Small Business and Service-Disabled Veteran-Owned Small Business.

5. HUBZone Small Business Concerns

Small Business offerors located in underutilized business zones, called "HUBZones," will be evaluated in accordance with FAR Clause 52.219-4, NOTICE OF PRICE EVALUATION PREFERENCE FOR HUBZONE SMALL BUSINESS CONCERNS, which is incorporated by reference in ARTICLE I.3. of this solicitation. Qualified HUBZone firms are identified in the Small Business Administration website at <http://www.sba.gov/hubzone>.

6. Extent of Small Disadvantaged Business Participation

In accordance with FAR Subpart 15.304(c)(4), the extent of participation of Small Disadvantaged Business (SDB) concerns in performance of the contract in the authorized NAICS Industry Subsectors shall be evaluated in unrestricted competitive acquisitions expected to exceed \$550,000 (\$1,000,000 for construction) subject to certain limitations (see FAR 19.1202-1 and 19.1202-2(b)). The dollar amounts cited above include any option years/option quantities that may be included in this solicitation. The definition of a "small disadvantaged business" is cited in FAR 19.001.

The factor entitled "Extent of Small Disadvantaged Business Participation" as set forth under the Evaluation Criteria in Section M shall be used for evaluation purposes.

The Department of Commerce determines, on an annual basis, by Subsectors, as contained in the North American Industry Classification System (NAICS) codes, and region, if any, the authorized SDB procurement mechanisms and applicable factors (percentages). The NAICS codes can be found at: <http://www.sba.gov/size>

The Department of Commerce website for the annual determination for NAICS codes* is: <http://www.arnet.gov/References/sdbadjustments.htm>.

** Note: Public Law 103-355 which authorized the SDB Price Evaluation Adjustment (PEA) and associated percentages/factors expired on December 9, 2004, therefore, the percentages shown at this website are no longer applicable.*

Offerors shall include with their offers, SDB targets, expressed as dollars and percentages of total contract value, in each of the applicable, authorized NAICS Industry Subsector(s). The applicable authorized NAICS Industry Subsector(s) for this project is (are) identified elsewhere in this RFP. A total target for SDB participation by the Prime Contractor, that includes any joint ventures and team members, shall be provided as well as a total target for SDB participation by subcontractors. In addition, offerors must provide information that describes their plans for meeting the targets set forth in their proposal. **This information shall be provided in one clearly marked section of the Business Proposal, which shall describe the extent of participation of SDB concerns in the performance of the contract.**

If the evaluation factor in this solicitation includes an SDB evaluation factor or subfactor that considers the extent to which SDB concerns are specifically identified, the SDB concerns considered in the evaluation shall be listed in any resultant contract. Offerors should note that addressing the extent of small disadvantaged business participation **is not in any way intended to be a substitute** for submission of the subcontracting plan, if it is required by this solicitation. An example of the type of information that might be given (in addition to the narrative describing the plan for meeting the targets) follows:

EXAMPLE

Targets for SDB Participation - NAICS Industry Subsector 223

	SDB Percentage of Total Contract Value	SDB Dollars
Total Contract Value- \$1,000,000	25%	\$250,000
SDB Participation by Prime	10%	\$100,000
(Includes joint venture partners and team arrangements)*		
SDB Participation by subcontractors	15%	\$150,000

*Note: FAR Subpart 9.6 defines "Contractor team arrangements" to include two or more companies forming a partnership or joint venture to act as a potential Prime Contractor, or a potential Prime Contractor who agrees with one or more companies to have them act as its subcontractors on a specific contract or acquisition program. For purposes of evaluation of the SDB participation factor, FAR 19.1202-4 requires that SDB joint ventures and teaming arrangements at the prime level be presented separately from SDB participation by subcontractors.

7. Total Compensation Plan

a. Instructions

1. Total compensation (salary and fringe benefits) of professional employees under service contracts may, in some cases, be lowered by recompetition of these contracts. Lowering of compensation can be detrimental in obtaining the necessary quality of professional services needed for adequate performance of service contracts. It is, therefore, in the best interest of the Government that professional employees, as defined in 29 CFR Part 541, be properly compensated in these contracts. All offerors as a part of their Business Proposal will submit a "Total Compensation Plan" (salaries and fringe benefits) for these professional employees for evaluation purposes.
2. The Government will evaluate the Total Compensation Plan to ensure that this compensation reflects a sound management approach and an understanding of the requirements to be performed. It will include an assessment of the offeror's ability to provide uninterrupted work of high quality. The total compensation proposed will be evaluated in terms of enhancing recruitment and retention of personnel and its realism and consistency with a total plan for compensation (both salaries and fringe benefits).
3. Evaluation for award, therefore, will include an assessment of the Total Compensation Plan submitted by each offeror.

b. Evaluation

1. Total Compensation Plan (Professional Employees)

In establishing compensation levels for professional employees, the total compensation (both salaries and fringe benefits) proposed shall reflect a clear understanding of the requirements of the work to be accomplished and the suitability of the proposed compensation structure to obtain and retain qualified personnel to meet mission objectives. The salary rates or ranges must recognize the distinct differences in professional skills and the complexity of varied disciplines as well as job difficulty. Proposals offering total compensation levels less than currently being paid by the predecessor Contractor for the same work will be evaluated, in addition to the above, on the basis of maintaining program continuity, uninterrupted work of high quality, and availability of required competent professional employees. Offerors are cautioned that instances of lowered compensation for essentially the same professional work may be considered a lack of sound management judgment in addition to indicating a lack of understanding of the requirement.

2. Cost (Professional Compensation)

Proposals which are unrealistically low or do not reflect a reasonable relationship of compensation to the professional job categories so as to impair the Contractor's ability to recruit and retain competent professional employees, may be viewed as reflecting a failure to comprehend the complexity of the contract requirements. The Government is concerned with the quality and stability of the work force to be employed on this contract. The compensation data required will be used in evaluation of the offeror's understanding of the contract requirements.

3. Other (Labor Relations)

An assessment of the potential for adverse effect upon performance and maintenance of the required number of professional employees with requisite skills resulting from an unrealistically low compensation structure will also be made.

4. Federal Acquisition Regulation Clauses incorporated by Reference

FAR Clause 52.222-46, Evaluation of Compensation for Professional Employees (FEBRUARY 1993).

8. Earned Value Management System

IMPORTANT NOTE TO OFFERORS: The following information shall be addressed in a separate section of the Business Proposal entitled, "Earned Value Management System."

- a. This resulting contract will be a Tier 1 information technology investment and must apply Earned Value Management (EVM) principles for tracking investment cost, schedule, and performance in full compliance with American National Standards Institute Electronic Industries Alliance (ANSI/EIA) Standard 748 A (Criteria 1 32).
- b. Earned Value Management (EVM) is a project management system used by the Contractor to effectively integrate the project technical scope of work with schedule and cost elements for optimum project planning and control. The qualities and operating characteristics of earned value management systems are described in American National Standards Institute (ANSI)/ Electronic Industries Alliance (EIA) Standard 748 A 1998, Earned Value Management Systems, approved: May 19, 1998, Reaffirmed: August 28, 2002.
- c. The offeror shall provide documentation that the Contracting Officer has recognized that the proposed earned value management system (EVMS) complies with the EVMS guidelines in ANSI/EIA Standard 748.

- d. If the offeror proposes to use a system that does not meet the requirements of paragraph (a) of this provision, the offeror shall submit a comprehensive plan for compliance with the EVMS guidelines.
1. The plan shall--
 - i. Describe the EVMS the offeror intends to use in performance of the contracts;
 - ii. Distinguish between the offeror's existing management system and modifications proposed to meet the guidelines;
 - iii. Describe the management system and its application in terms of the EVMS guidelines;
 - iv. Describe the proposed procedure for administration of the guidelines, as applied to subcontractors; and
 - v. Provide documentation describing the process and results of any third party or self evaluation of the system's compliance with the EVMS guidelines.
 2. The offeror shall provide information and assistance as required by the Contracting Officer to support review of the plan.
 3. The Government will review the offeror's plan for EVMS before contract award.
 4. The offeror's EVMS plan must provide milestones that indicate when the offeror anticipates that the EVM system will be compliant with the ANSI/EIA Standard -748 guidelines.
- e. The offeror shall identify the major subcontractors, or major subcontracted effort if major subcontractors have not been selected, planned for application of the guidelines. The prime Contractor and the Government shall agree to subcontractors selected for application of the EVMS guidelines.
- f. The Government will conduct an Integrated Baseline Review (IBR) prior to contract award. The objective of the IBR is for the Government and the Contractor to jointly assess technical areas, such as the Contractor's planning, to ensure complete coverage of the contract requirements, logical scheduling of the work activities, adequate resources, methodologies for earned value (budgeted cost for work performed (BCWP)), and identification of inherent risks.

Offerors [] **Will** [X] **Will Not** be directly compensated for the costs of participating in a pre-award IBR.

9. Other Administrative Data

a. Property

1. It is HHS policy that Contractors will provide all property necessary for contract performance. Exception may be granted to provide Government property (Government-furnished or Contractor-acquired), but only when approved by the Contracting Officer. If the offeror requests that Government property be provided, other than that specified under "Government Furnished Property," below, the proposal must include a comprehensive justification addressing the following items:
 - a. State why the property is essential to contract performance and whether the property will be used exclusively for this contract.

- b. Describe other alternatives (e.g., purchase, lease, etc.) pursued and why they were not viable options.

2. Government Property

The offeror shall identify Government property in its possession which it proposes to use in the performance of the prospective contract as follows:

- a. A list or description of all Government property that the offeror or its subcontractors propose to use on a rent-free basis. The list shall identify the accountable contract under which the property is held and the authorization for its use (from the Contracting Officer having cognizance of the property);
- b. The dates during which the property will be available for use (including the first, last, and all intervening months) and, for any property that will be used concurrently in performing two or more contracts, the amounts of the respective uses in sufficient detail to support prorating the rent;
- c. The amount of rent that would otherwise be charged in accordance with FAR 52.245-9, Use and Charges; and
- d. The voluntary consensus standard or industry leading practices and standards to be used in the management of Government property, or existing property management plans, methods, practices, or procedures for accounting for property.

NOTE: The Contracting Officer will consider any potentially unfair competitive advantage that may result from the Contractor possessing Government property, and for evaluation purposes only, adjust the offers using a rental equivalent evaluation factor, as appropriate.

3. Government-Furnished Property

A Listing of Government Furnished Property is provided in Section J - Solicitation Attachments of this solicitation

- 4. The management and control of any Government property shall be in accordance with the HHS Publication entitled, Contractors Guide for Control of Government Property, which can be found at: <http://knownet.hhs.gov/log/AgencyPolicy/HHSLogPolicy/contractorsguide.htm>

b. Submission of Electronic Funds Transfer Information with Offer, FAR Clause 52.232-38 (MAY 1999)

The offeror shall provide, with its offer, the following information that is required to make payment by electronic funds transfer (EFT) under any contract that results from this solicitation. This submission satisfies the requirement to provide EFT information under paragraphs (b)(1) and (j) of the clause at 52.232 34, Payment by Electronic Funds Transfer Other than Central Contractor Registration.

- (1) *The solicitation number (or other procurement identification number).*
- (2) *The offeror's name and remittance address, as stated in the offer.*
- (3) *The signature (manual or electronic, as appropriate), title, and telephone number of the offeror's official authorized to provide this information.*

- (4) *The name, address, and 9 digit Routing Transit Number of the offeror's financial agent.*
- (5) *The offeror's account number and the type of account (checking, savings, or lockbox).*
- (6) *If applicable, the Fedwire Transfer System telegraphic abbreviation of the offeror's financial agent.*
- (7) *If applicable, the offeror shall also provide the name, address, telegraphic abbreviation, and 9 digit Routing Transit Number of the correspondent financial institution receiving the wire transfer payment if the offeror's financial agent is not directly on line to the Fedwire and, therefore, not the receiver of the wire transfer payment.*

(End of Provision)

c. Financial Capacity

The offeror shall indicate if it has the necessary financial capacity, working capital, and other resources to perform the contract without assistance from any outside source. If not, indicate the amount required and the anticipated source.

d. Incremental Funding

An incrementally funded cost-reimbursement contract is a contract in which the total work effort is to be performed over a multiple year period and funds are allotted, as they become available, to cover discernible phases or increments of performance. The incremental funding technique allows for contracts to be awarded for periods in excess of one year even though the total estimated amount of funds expected to be obligated for the contract are not available at the time of the contract award. If this requirement is specified elsewhere in this RFP, the offeror shall submit a cost proposal for each year. In addition, the following provision is applicable:

Incremental Funding, HHSAR 352.232-75 (January 2006)

(a) It is the Government's intention to negotiate and award a contract using the incremental funding concepts described in the clause entitled Limitation of Funds as specified in FAR 52.232-22. Under the clause, which will be included in the resultant contract, initial funds will be obligated under the contract to cover the first year of performance. The Government intends to allot additional funds up to and including the full estimated cost of the contract for the remaining years of performance by contract modifications. However, the Government is not obligated to reimburse the Contractor for costs incurred in excess of the periodic allotments, nor is the Contractor obligated to perform in excess of the amount allotted.

(b) The Limitation of Funds clause to be included in the resultant contract, as specified in FAR 52.232-22, shall supersede the Limitation of Cost clause found in the Section I, Contract Clauses.

(End of provision)

e. Facilities Capital Cost of Money, FAR 52.215-16, (June 2003)

(This is applicable if you are a commercial organization.)

(a) Facilities capital cost of money will be an allowable cost under the contemplated contract, if the criteria for allowability in FAR 31.205-10(b) are met. One of the allowability criteria requires the prospective Contractor to propose facilities capital cost of money in its offer.

(b) If the prospective Contractor does not propose this cost, the resulting contract will include the clause Waiver of Facilities Capital Cost of Money.

(End of Provision)

If the offeror elects to claim this cost, the offeror shall specifically identify or propose it in the cost proposal for the contract by checking the appropriate box below.

[] Fac Cap Cost of Money (Has) *The prospective Contractor **has** specifically identified or proposed facilities capital cost of money in its cost proposal and elects to claim this cost as an allowable cost under the contract. Submit Form CASB-CMF (see FAR 31.205-10).*

[] Fac Cap Cost of Money (Has Not) ***has not** specifically identified or proposed facilities capital cost of money in its proposal and elects not to claim it as an allowable cost under the contract.*

10. Qualifications of the Offeror

You are requested to submit a summary of your "General Experience, Organizational Experience Related to this RFP, Performance History and Pertinent Contracts."

a. General Experience

General experience is defined as general background, experience and qualifications of the offeror. A discussion of proposed facilities which can be devoted to the project may be appropriate.

b. Organizational Experience Related to the RFP

Organizational experience is defined as the accomplishment of work, either past or on-going, which is comparable or related to the effort required by this RFP. This includes overall offeror or corporate experience, **but not** the experience and/or past performance of individuals who are proposed as personnel involved with the Statement of Work in this RFP.

c. Performance History

Performance history is defined as meeting contract objectives within **delivery** and **cost schedules** on efforts, either past or on-going, which is comparable or related to the effort required by this RFP.

d. Pertinent Contracts

Pertinent contracts is defined as a listing of each related contract completed within the last three years or currently in process. The listing should include: 1) the contract number; 2) contracting agency; 3) contract dollar value; 4) dates contract began and ended (or ends); 5) description of contract work; 6) explanation of relevance of work to this RFP; 7) actual delivery and cost performance versus delivery and cost agreed to in the contract(s). For award fee contracts, separately state in dollars the base fee and award fee available and the award fee actually received. The same type of organizational experience and past performance data should be submitted.

e. Pertinent Grants

List grants supported by the Government that involved similar or related work to that called for in this RFP. Include the grant number, involved agency, names of the grant specialist and the Science Administrator, identification of the work, and when performed.

You are cautioned that omission or an inadequate or inaccurate response to this very important RFP requirement could have a negative effect on the overall selection process.

Experience and past performance are factors which are relevant to the ability of the offerors to perform and are considered in the source selection process.

11. **Subcontractors**

If subcontractors are proposed, please include a commitment letter from the subcontractor detailing:

- a. Willingness to perform as a subcontractor for specific duties (list duties).
- b. What priority the work will be given and how it will relate to other work.
- c. The amount of time and facilities available to this project.
- d. Information on their cognizant field audit offices.
- e. How rights to publications and patents are to be handled.
- f. A complete cost proposal in the same format as the offeror's cost proposal.

Note: Organizations that plan to enter into a subcontract with an educational concern under a contract awarded under this RFP should refer to the following Web Site for a listing of clauses that are required to be incorporated in Research & Development (R&D) subcontracts with educational institutions:

<http://ocm.od.nih.gov/contracts/rfps/FDP/FDPclausecover.htm>

12. **Proposer's Annual Financial Report**

A copy of the organization's most recent annual report must be submitted as part of the business proposal.

13. **Representations and Certifications - SECTION K**

One copy of SECTION K (which includes FAR Clause 52.204-8 Annual Representations and Certifications) shall be completed and be signed by an official authorized to bind your organization. Additionally, a completed copy of SECTION K shall be submitted from any proposed subcontractor. SECTION K can be found at: <http://rcb.cancer.gov/rcb-internet/wkf/sectionk.pdf>

14. **Travel Costs/Travel Policy**

a. **Travel Costs - Commercial**

Costs for lodging, meals, and incidental expenses incurred by Contractor personnel shall be considered to be reasonable and allowable to the extent they do not exceed on a daily basis the per diem rates set forth in the Federal Travel Regulations, General Services Administration (GSA). Therefore, if travel costs are applicable and proposed by offerors, please be advised that they shall be calculated using the per diem rate schedule as established by GSA. Reimbursement of travel costs under any contract awarded from this RFP shall be in accordance with FAR 31.205-46.

b. **Travel Policy**

One copy of the offeror's (and any proposed subcontractor's) written travel policy shall be included in the business proposal (original only). If an offeror (or any proposed subcontractor) does not have a written travel policy, the offeror shall so state.

SECTION M - EVALUATION FACTORS FOR AWARD

1. GENERAL

The major evaluation factors for this solicitation include technical (which encompasses experience and past performance factors) cost/price factors and Small Disadvantaged Business (SDB) Participation. Although technical factors are of paramount consideration in the award of the contract, cost/price and SDB participation is also important to the overall contract award decision. All evaluation factors other than cost or price, when combined, are significantly more important than cost. The Government intends to make an award(s) to that offeror whose proposal provides the best overall value to the Government.

The evaluation will be based on the demonstrated capabilities of the prospective Contractors in relation to the needs of the project as set forth in the RFP. The merits of each proposal will be evaluated carefully. Each proposal must document the feasibility of successful implementation of the requirements of the RFP. Offerors must submit information sufficient to evaluate their proposals based on the detailed criteria listed below.

2. MANDATORY QUALIFICATION CRITERIA

Listed below are mandatory qualification criteria. The Offeror must provide a copy of the appraisal that certifies that it has achieved CMMI Level III or higher IN ONE CLEARLY MARKED SECTION OF ITS PROPOSAL, additionally the offeror must indicate its CMMI Level certification on the face page of both the technical and business proposal.

The qualification criteria establishes conditions that must be met at the time of receipt of proposals by the Contracting Officer in order for your proposal to be considered any further for award.

CMMI Level 3 Certification - The Prime Offeror must be functioning at the CMMI level 3 certification stage.

3. EVALUATION OF OPTIONS AND AWARD TERMS

It is anticipated that any contract awarded from this solicitation will contain both option and award term provision(s) and period(s).

In accordance with FAR Clause 52.217-5, Evaluation of Options, (July 1990), the Government will evaluate offers for award purposes by adding the total price for all options to the total price for the basic requirement, except when it is determined in accordance with FAR 17.206(b) not to be in the Government's best interests. Evaluation of options will not obligate the Government to exercise the option(s).

4. TECHNICAL EVALUATION CRITERIA

The evaluation criteria are used by the technical evaluation committee when reviewing the technical proposals. The criteria below are listed in the order of relative importance with weights assigned for evaluation purposes.

A. Personnel and Experience 40%

1. Qualifications of Senior Staff (Principal Investigator, Project Director, Head, Software Engineer/ Senior Analysts, Subject Matter Experts and Lead Software Developers and Statistical Programmer)

- Knowledge and experience in developing, implementation and management of a large scale (>1 million lines of code or equivalent) software systems in a biomedical environment.
- Demonstrated experience in the development, implementation, management, and maintenance of large scale database systems, in an NT Server, RAID-5 Server and Oracle® Environment.
- Knowledge of applying CMMI best practices
- Experience in the use of CASE tools, such as Oracle Designer 2000®, Oracle Developer 2000®.
- Experience in the development, implementation and maintenance of "Client Server" applications.
- Knowledge and experience with Windows NT Server and application within a LAN environment.
- Experience in development, implementation and maintenance of 'Web' applications, and Web services within the context of a service oriented architecture.
- Knowledge and experience with the latest Internet technologies (i.e. XML, HTML, JAVA).
- Knowledge and experience with the latest Internet security tools and measures.
- Knowledge and experience with change management applications and processes required for a large software development effort that will involve system integration, convergence and legacy migration activities.
- Knowledge of caGRID tools and caBIG™ compatibility requirements for bronze, silver, and gold compatibilities.
- Knowledge of best practice for IT and data governance to support a balanced scorecard approach for strategic alignment.
- Knowledge of best practice for implementing and sustaining data quality at the enterprise level.
- Knowledge in applying earned value management for IT projects to meet Capital Planning Investment Control (CPIC) requirements.
- Knowledge of biomedical informatics within the context of clinical trial management systems environment.

2. Qualification of non-senior professional staff members (programmers, programmer/analysts).

- Knowledge and experience in developing, implementation and management of a large-scale (>1 million lines of code or equivalent) software development effort in a biomedical environment.
- Experience with recognized standard systems development methodology.
- Training and experience of the Software engineers in the use of Oracle CASE Tools, (i.e. Oracle Designer 2000® and Oracle Developer 2000®.)
- Knowledge and experience of the Software Engineers in the development and maintenance of large scale database systems in an NT Server, RAID-5 Server, Oracle, and Oracle WEB server environments.
- Demonstrations of the Software testers documented training and experience in the testing and validation of newly developed software.
- Experience with processes to assure quality of data captured and maintained in a large-scale database.
- Experience with development and maintenance of support materials and other documentation for custom software. Including mature change management, configuration management, help desk management, test management, etc.
- Demonstrated experience with knowledge acquisition, joint applications development/rapid application deployment methods.
- Experience with the development of promotional materials to demonstrate custom software applications.
- Experience with development, implementation and maintenance of training programs for custom software.
- Knowledge and experience with common Web page development tools.

3. Combined range of experience

- Breadth and depth of composite experience of the proposed team members with the software products used by CTEP.
- Composite experience of the proposed team members in bio-medical information management and automation.

- Knowledge and experience in developing, implementation and management of a large scale (>1 million lines of code or equivalent) software systems in a biomedical environment.
- Demonstration of ability to work with other contractors on joint system integration projects.

4. *Demonstrated experience of proposed staff working together as a team. Evidence of a stable workforce and ability to recruit and retain staff.*

5. *Demonstrated availability of personnel.*

B. Adequacy of Technical Approach and Understanding of the Project 40%

1. Demonstrated experience of the organization as a whole which indicates history with leading, participating, and contributing to various projects of equivalent scope, size and mission.

2. Demonstration of an understanding of the needs of the project. Demonstration of an understanding of the oncology community and cancer clinical research. Explanation of the methods and approach for accomplishing the tasks outlined in the Statement of Work (Section 1 to 8) in a secure, flexible and user-friendly environment. Ability to meet with CTEP personnel on short notice.

3. Demonstrated understanding of Quality Assurance (QA) methods, goals and objectives. Specific descriptions of how the work performed will meet or exceed Quality Assurance goals shall be included. Demonstration of approach to development of a QA plan, evaluation of activities covered in the QA plan, and method used to update the QA plan.

4. Demonstrate a plan to optimize data quality and timeliness of projects and tasks as detailed in the Statement of Work. Including provision of a quality assurance plan to demonstrate overall project efficiency, productivity and cost-effectiveness.

5. Demonstration of the ability to provide daily contact with CTEP staff by the Project Managers, Head Software Engineer, System Analysts, Programmers, Data Technicians, and IT Security Managers to discuss and advise on technical problems and to review data for all CTEP systems.

6. Demonstration of a management plan which will provide CTEP Project Officers up to date financial, project/subproject status, and personnel information. The plan should include methods to demonstrate cost of ownership, earned value management, and multiple baseline data, IT enterprise evolution utilizing an enterprise unified process approach.

7. Demonstrated experience with best business practices utilizing CMMI level 3 and associated specific practice tools (i.e., rational unified process, enterprise unified process).

8. Demonstration of a transition plan that would support a smooth transfer of responsibility from the incumbent Contractor.

9. Plan for providing training, including provision of facilities and equipment for hands-on computer training.

C. Past Performance 20%

1. The Government will evaluate the offeror's past performance based on information obtained from references provided by the offeror, other relevant past performance information obtained from other sources known to the Government, and any information supplied by the offeror concerning problems encountered on the identified contracts and corrective action taken.

2. The Government will assess the relative risks associated with each offeror. Performance risks are those associated with an offeror's likelihood of success in performing the acquisition requirements as indicated by that offeror's record of past performance.

3. The Government will consider the currency and relevance of the information, source of the information, context of the data, and general trends in the offeror's performance.
4. The lack of a relevant performance record may result in an unknown performance risk assessment, which will neither be used to the advantage nor disadvantage of the offeror.
5. Listed below are past performance subfactors and the weights to be used for evaluation purposes.
6. The past performance subfactors are listed below in order of relative importance. These subfactors will be used to evaluate the quality of past performance.
 - a. Record of success in activities involving clinical trials, oncology, and other biomedical fields
 - b. Record of success in contracts with bioinformatics, particularly large scale activities.
 - c. Record of success in contracts providing development, maintenance, and help desk support for IT networks.
 - d. Record of cost containment in providing services under contract.

5. EXTENT OF SMALL DISADVANTAGED BUSINESS PARTICIPATION

SDB participation will not be scored, but the Government's conclusions about overall commitment and realism of the offeror's SDB Participation targets will be used in determining the relative merits of the offeror's proposal and in selecting the offeror whose proposal is considered to offer the best value to the Government.

The extent of the offeror's Small Disadvantaged Business Participation Targets will be evaluated before determination of the competitive range. Evaluation of SDB participation will be assessed based on consideration of the information presented in the offeror's proposal. The Government is seeking to determine whether the offeror has demonstrated a commitment to use SDB concerns for the work that it intends to perform.

Offers will be evaluated on the following sub-factors:

- a. Extent to which SDB concerns are specifically identified
- b. Extent of commitment to use SDB concerns
- c. Complexity and variety of the work SDB concerns are to perform
- d. Realism of the proposal
- e. Past performance of offerors in complying with subcontracting plan goals for SDB concerns and monetary targets for SDB participation
- f. Extent of participation of SDB concerns in terms of the value of the total acquisition.

6. EVALUATION OF BUSINESS PROPOSAL

6. A cost realism analysis will be conducted to determine whether the estimated proposed cost elements are realistic for the work to be performed; reflect a clear understanding of the requirements; and are consistent with the unique methods of performance and materials described in the offeror's technical proposal. Proposed costs will be evaluated for reasonableness, allowability, and allocability. This analysis is intended to determine the degree to which costs and fee included in the proposal are fair and reasonable.